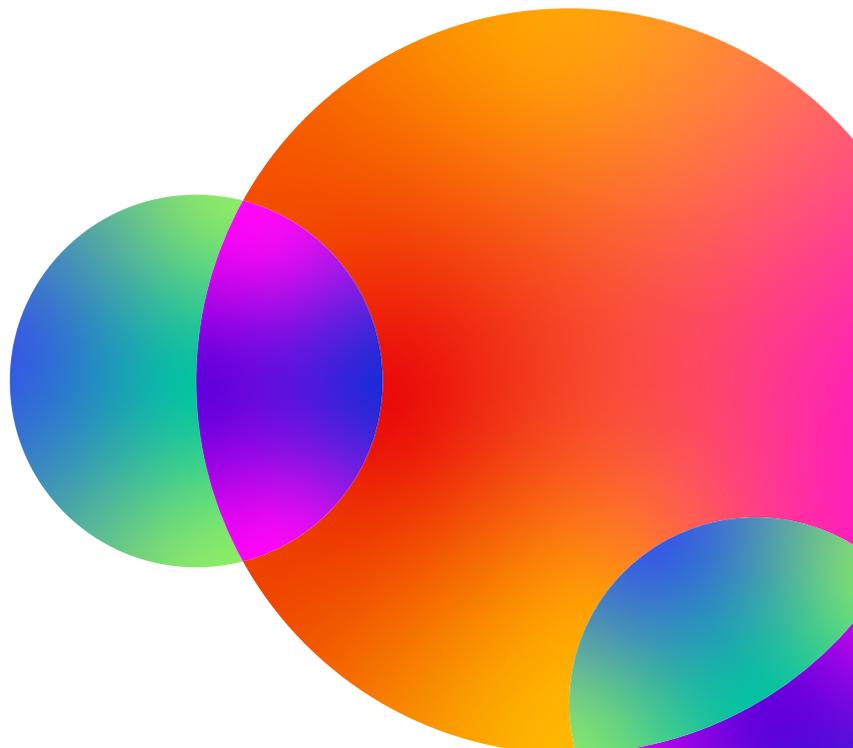


# Clinical Alignment Via Decision Support

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# Abstract

Value analysis has long been the process used to make well-informed, evidence-based decisions in healthcare organizations. Today, the ability to make expeditious, defensible decisions that align with value-based care, and subsequently value-based payment methods, has become one of the most important functions in every healthcare organization. However, COVID-19 exposed two fundamental realities particularly pertinent to value analysis teams and hospital leaders. Those individuals and others charged with evaluating their product introduction strategies should take heed:

1. Value-based decisions cannot be made, and value-based care cannot be achieved, without high levels of clinical alignment.
2. The majority of decision-making processes across health systems have proven to be inadequate in handling modern complexities such as mitigating risk, protecting governance, and ensuring compliance across the continuum.

As a result, health systems are evaluating how they can involve the right people, at the right time, and in the right capacity to approach evidence-based decision making within a digital framework. Key to this discussion is how clinical evidence and operational data combined can be a foundation for clinical alignment and serve as key components of the decision-making infrastructure (technologies, tools, etc.) that support virtual workflows and standardization.



## Clinical Alignment: A Definition

Clinical alignment is unique to traditional value analysis frameworks, as it is rooted in high levels of executive and clinical engagement, and promotes an outcomes-focused culture across the organization. Clinical alignment is guided by interdisciplinary partners working in coordination to pursue the common goal of providing exceptional value and evidence-based care. A sign of clinical alignment is when decisions consistently coordinate with a standard of care defined and supported by the larger organizational culture, as opposed to maintaining event-based decision making.



# Taking a Step Back From the Traditional Value Analysis Committee

Historically, the traditional value analysis committee has been highly structured, maintaining in-person meetings, with the majority of knowledge and processes centralized to a relatively small stakeholder group. And, while committees may be large in composition, critical expertise from clinical, financial, and operational perspectives may not be present. However, disruption in supply chain and care delivery has challenged this traditional approach. During COVID-19, physicians and other clinicians were exposed to supply chain realities like never before, thus requiring them to elevate their engagement and provide clinical validation for the allocation of products. This presented an inflection point in the healthcare landscape, and in many cases, opened the door for clinical alignment between stakeholders traditionally lacking accord. Marking another significant shift, the collapse of in-person meetings presented challenges for systems operating without established virtual capabilities in their decision-making infrastructure. In these cases, a lack of flexibility, barriers to data visibility, and an inability to make expedient decisions crippled teams across the country.

As an industry, we would be remiss in failing to take a step back to recognize the significant shifts that took place during COVID-19 in both the architecture of and activities among value analysis committees and related stakeholders. For those of us who have seen the devastating realities of supply chain duress in the field, it's clear that the impact has extended beyond individual processes and product decisions. Moving forward, what does this mean for health systems with a strategic, outcomes-focused strategy? Strong governance is critical for process continuity; risk mitigation is central to patient outcomes; and compliance is a non-negotiable factor for maintaining objective, centralized decision making. Without mature governance, risk awareness, and compliance mechanisms, supply chain simply doesn't have the infrastructure to withstand the complexity of the modern healthcare ecosystem, never mind expecting it to contribute to clinical alignment or excel in a virtual environment.

To move forward as an aware and equipped industry, we must first pause and answer critical questions about current value analysis methodologies, including the following:

- Does the traditional model, utilized by the great majority of health systems, afford the level of flexibility required to meet today's complex, fluctuating challenges?
- How do we strategically move forward to better engage clinical stakeholders?
- What processes do we need to reevaluate?
- What foundational data have we historically neglected to consider?
- How have we framed and understood risk in the new product introduction process?
- What infrastructure do we need to build to consider that data?
- And, critical to maturing value analysis programs: How well were we able to pivot to a virtual environment and maintain decision-making integrity?

In an effort to evolve from an old-world approach surrounding new product introduction to a new-world, virtual infrastructure, core components must be considered.



## Clinical Alignment: Sometimes Mystifying, Always Critical

In a contemporary healthcare ecosystem, clinical alignment is required to achieve strategic, financial, and clinical objectives. A focus on value-based care and quality excellence makes process collaboration, in partnership with strong data, a non-negotiable. An underlining theme is the need for a new level of flexibility and willingness to challenge perspectives, accomplished through collaboration on how to deliver the best value across the continuum. During COVID-19, the disruption in daily workflows and responsibilities opened a rare window of opportunity to expose and address a deep lack of alignment among stakeholders. Ultimately, clinical and non-clinical stakeholders are collaborative partners in improving patient care, elevating population health, increasing value, and sharing risk. The community has seemingly agreed to this standard on paper, but the supporting culture has not seen the evolution that progress demands.

In a new-world context, the larger healthcare organization, as well as physicians, clinicians, supply chain, value analysis, vendors, payers, etc., all take part in this shared responsibility. In forward-looking organizations, this responsibility is borne out in greater acceptance of shared risk. COVID-19 and the complexities it wrought have proved that organizations can no longer function in siloes; without clinical alignment, organizations are not equipped to adapt and make strategic decisions expeditiously. Moving forward, clinical alignment will require a new level of collaboration, flexibility, digital capabilities, data-sharing, and dedication to cultural change.

However, while the need for strong clinical alignment is clear, the pathway to its improvement has historically been considered more of an unobtainable ideal than an actionable process.

# Common Challenges to Achieving Clinical Alignment

While every healthcare organization varies with regard to its leadership and committee structures, culture, values, mission, and other factors, there are common hurdles to the ability to achieve clinical alignment, including the following well-documented factors:

- There is poor cultural alignment and a lack of clarity surrounding organizational goals and norms
- Organizational goals are not well-socialized and/or are not visibly supported by leaders
- The physician/clinician requestor does not have a defensible “why” behind a product request
- Clinical and non-clinical stakeholders operate with contradictory objectives that motivate decision making
- Inconsistent communication standards and event-based interactions/decisions are normalized
- Processes lack engagement mechanisms and standardization
- Stakeholders operate with different standards or sources of data
- Data is not democratized across the organization
- Siloed processes support a lack of transparency throughout the decision-making process
- Physicians follow a culture of taking on the limited role of case-by-case product promoters rather than system-wide clinical process champions
- Clinical expertise and data are not shared/considered at the start of the request/review process





# Principles for Improving Clinical Alignment

## Beginning with executive buy-in and leadership

For clinical alignment to occur, all stakeholders in the clinically integrated supply chain must have a clear understanding of current challenges and organizational goals that extend beyond financial objectives. Achieving this state requires high levels of executive communication and follow-through. If systemwide values, clinical goals, and an outcomes-focused culture are well socialized, shifting legacy behavioral patterns becomes a more realistic endeavor.

## Operating with the same “why”

Unfortunately, supply chain teams and processes are often seen as gatekeepers, perceived as exclusively prioritizing financial objectives via improving upfront cost without clinical input. Frequently, once organizations recognize they have an issue with out-of-control physician preference item (PPI) spend and a lack of standardization, there is a propensity to immediately stunt new product introduction, jump to cutting costs, and prioritizing less expensive products. The challenge is that less-expensive products don't necessarily translate to increased value. When this is the standard, leaders are focused on cost savings but may not demonstrate buy-in for operating under a clinical framework. However, prioritizing upfront cost is only a momentary band-aid, if not a significant injury to decision making, as it fails to recognize clinical outcomes and total value. When organizations are stuck operating within this framework, the foundation of clinical alignment does not exist. Yet, while supply chain and value analysis may be too heavily focused on cost avoidance, on the other side of the coin, clinical stakeholders are often detached from supply chain realities or may not be exposed to the aggregated data necessary to understand the full value picture. In part, this is due to a lack of formal supply chain education in medical school and residency, a gap that unfortunately works to maintain the status quo. Rather, if physicians operate under a truly outcomes-focused framework, they are committed to contributing to the highest level of patient care through decisions that objectively promote the best outcomes, which may not align with PPI spend.

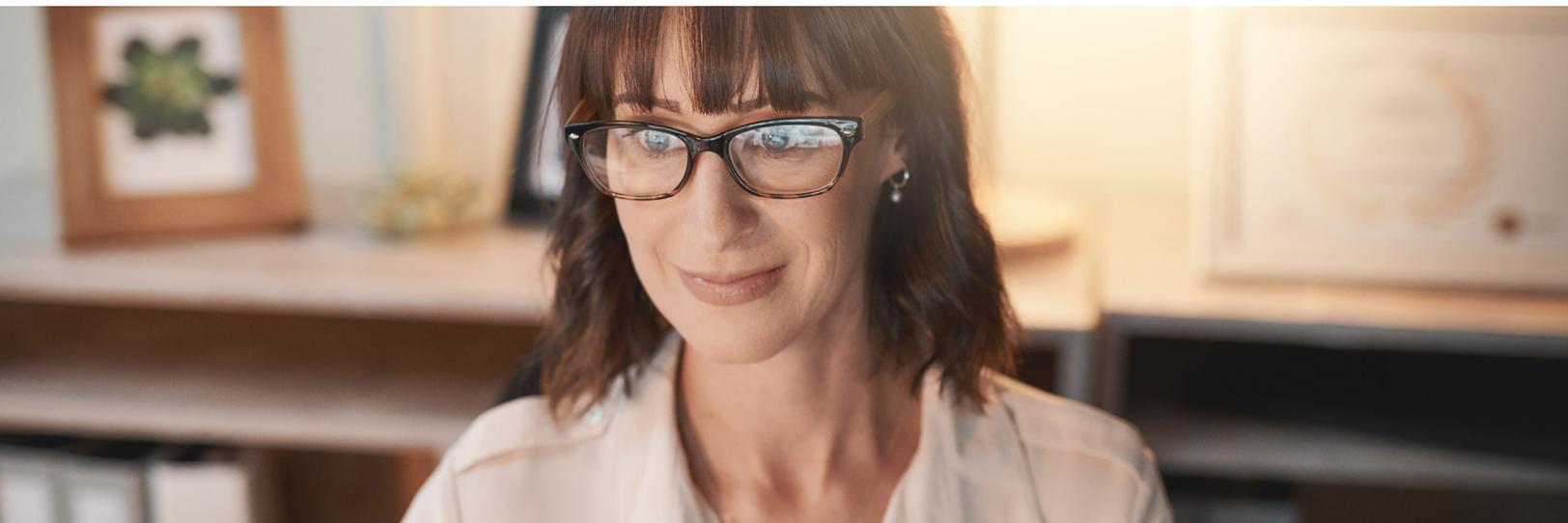
Rallying around the same outcomes-focused “why” opens the door to improve clinical alignment. As a result, value analysis is seen as a strategic factor in improving clinical outcomes—rather than a detached hurdle. To move forward, all parties must commit to expanding their understanding of new product introduction—an understanding that reduces variability and keeps up with the demands of value-based care. When systems operate with the same “why,” they often find that the collective focus around improving outcomes may ultimately work to reduce costs by delivering additional value. This represents true clinical integration.



## Allowing data to make the decisions

The circulation and evaluation of high-quality data is the ultimate foundation for clinical alignment and evidence-based decision making. Physicians are compelled by high-quality, objective evidence that speaks to patient outcomes. When engaging physicians and clinicians, supply chain teams must understand the patient-centric lens through which clinical stakeholders view product decisions. For advanced value analysis teams, evidence is also the foundation for value-based decision making and deepening mutual understanding of risk. Therefore, a primary pathway for clinical alignment is found in evidence. Advanced healthcare organizations understand that communicating and collaborating over clinical ROI is much more powerful and effective than navigating friction surrounding upfront financial cost, a data point that may or may not be reflective of ultimate value.

Success requires removing egos by operating with and prioritizing the same set of unbiased, transparent, and aggregated data. To achieve alignment across diverse stakeholder groups and to diminish risk, it's crucial to evaluate not only comprehensive clinical evidence, but also examine benchmarked data and information on safety, usage, and spend. Ultimately, a new product is not just a device, but an instrument to impact patient care. When organizations are data driven, evidence is not only a component of decision making, but it also serves as the foundation of holistic product introduction and management. For mature organizations, data is readily accessible, standardized, frequently utilized, and disseminated across stakeholder groups for visibility and collaboration. While this approach requires a sophisticated infrastructure, allowing data to make decisions opens a clear pathway for clinical alignment.





# Standardization and Governance: Decision-Making Levers for Clinical Alignment

To achieve clinical alignment and pivot to a new-world approach to value analysis, it is critical to standardize processes and improve governance.

A standardized approach is beneficial in:

- Reducing product, process, and care delivery variation, which in turn helps to improve outcomes and efficiency while minimizing costs and risks
- Enabling efficiency and streamlined processes rather than one-off interactions, which lead to increased costs and variation
- Elevating organizational clarity and alignment surrounding systemwide goals
- Reinforcing best practices, ultimately supporting clinical transformation
- Bringing additional value to patients, as stakeholders work as partners via a standardized approach



# Key Components of a Standardized Approach to Decision

## Developing strong governance and policies

Why is strong governance critical to modern supply chain processes? Improving clinical alignment and standardization may be common goals throughout the continuum, but the structured mechanisms supporting these efforts will often determine their relative level of compliance and success. The journey to high levels of compliance is guided by the governance levers that enable efficient, accountable decision making. To operationalize best practices, processes need to be well-socialized and practical for stakeholders. For example, reducing waste—a core component of value-based care—requires systemwide request, usage, and performance data; clinical insight; and an easily accessible infrastructure in which to evaluate and practice continued audits. To unify all of these elements consistently, systems must standardize toward what is best practice using actionable mechanisms. However, the journey toward what is best practice first requires a comprehensive current-state evaluation. Understanding and documenting current processes via a thorough review of pain points alongside specific goals provides the visibility needed to optimize and standardize the right processes while introducing supportive mechanisms.

Health systems must ask:

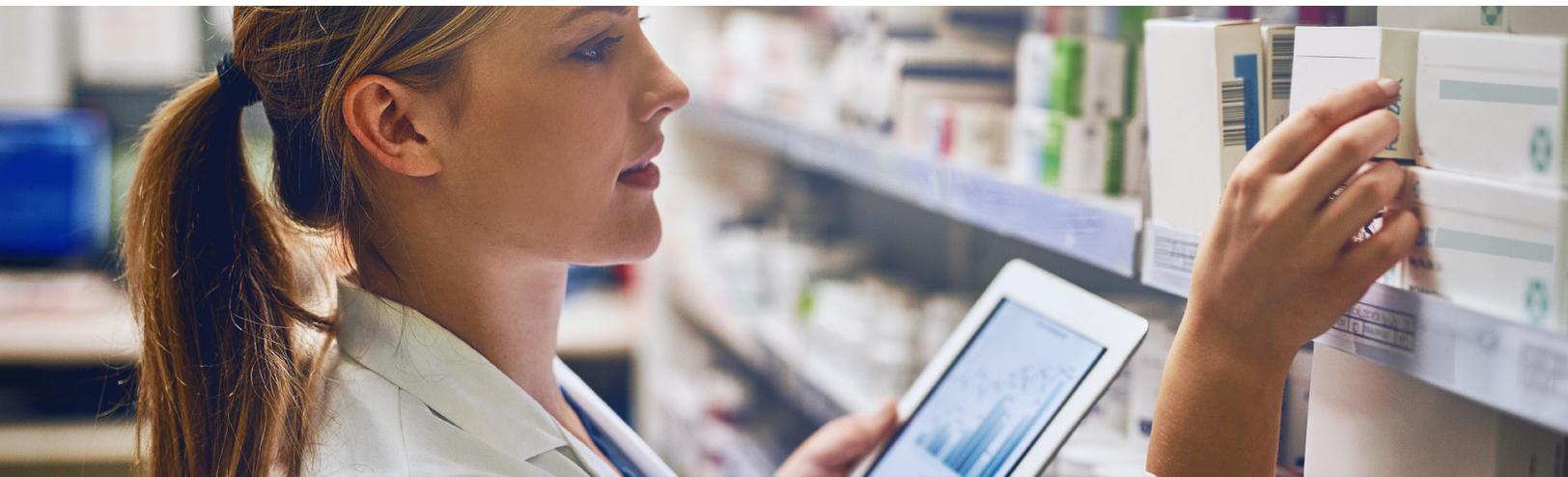
- What does governance currently look like for my organization?
- Does our current infrastructure encourage compliance and arm stakeholders with the tools and user-friendly workflows to execute tasks with efficacy?
- What does improving governance mean in practice?
- Who should be involved in crafting and leading these mechanisms to support policies?
- Is our current infrastructure effective in protecting governance given the challenges my organization is experiencing today?
- To what extent has technology played a role in supporting governance?

## Change management surrounding larger organizational goals

No matter how mature the organization, developing and maintaining clinical alignment is challenging. Very few systems have been able to break the status quo and achieve a culture of clinical alignment via a standardized approach. To avoid regression to siloed activities, value analysis must maintain not only financial responsibility, but decision-making authority in partnership with clinical stakeholders. A standardized approach recognizes that value analysis is not only accountable for cost, but also contributes to patient outcomes. When all stakeholders are focused on the same goal of improving quality of care with shared accountability, then collaborative, evidence-based decision making is possible. Just as it would be for any process improvement involving diverse stakeholders, ongoing change management is required to move the needle and shape behavior.

## Centralization and representation

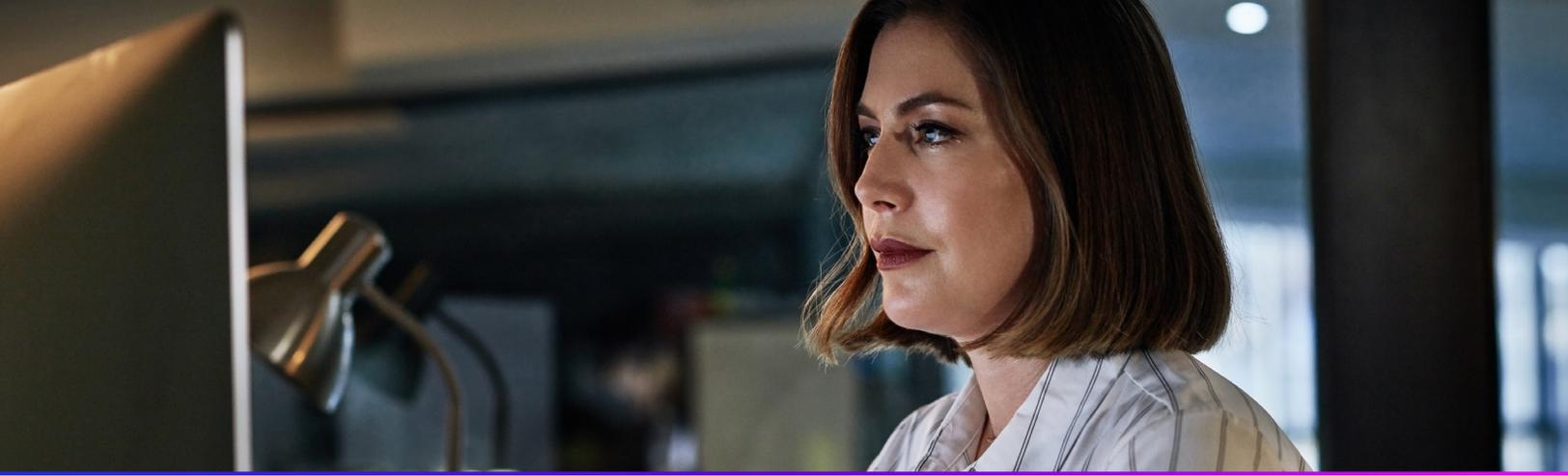
Centralized workflows and processes are critical to achieving and maintaining standardization, especially for large IDNs. For example, maintaining a single point of entry for new product requests is a foundational aspect of protecting decision-making governance. The challenge here is maintaining strong centralization without stifling collaboration, a challenge that requires streamlined processes and accessible evaluation tools to maintain both organization and engagement. Similarly, as the healthcare ecosystem grows, so does the diversity of stakeholders involved in the new product introduction process. Whether that is suppliers taking on additional risk or physicians serving as process champions rather than exclusively product champions, the breadth of engagement is expanding. In essence, moving forward with standard processes requires that we consider how to involve the right people, at the right time, and in the right way.



## Standardizing the supplier relationship

While the strategy of increasing physician engagement in value analysis has gained general industry consensus, there may be less agreement surrounding the role of suppliers in the new product introduction process. For most organizations, maintaining arm's length in the relationship has been considered best practice. Meanwhile, for smaller hospitals, a lack of bandwidth and resources necessitate reliance on supplier-provided data. In either instance, the supplier maintains a central role in the new product introduction ecosystem and is pursuing physician relationships throughout the process. It is important to preface that not all supplier-led interactions or provided data are detriments to decision making. However, to reduce risk and bias, and to make evidence-based decisions, there must be a standard, systemwide process that incorporates centralized product information. From a supplier policy perspective, this means standardizing supplier engagement with both clinical and non-clinical stakeholders while requiring that all available product data is provided upfront. When the supplier is clear in their role and physicians buy in to the standardized role of the supplier, compliance is elevated.





# Digital Infrastructure for Decision Support

Thus far, we have established clinical alignment and standardization as key pillars in transforming an old-world decision-making process into a new-world value analysis infrastructure. However, neither objective can be fully realized in a contemporary context without a flexible, dynamic, and virtual approach to engagement and decision-making.

COVID-19 was an inflection point in the healthcare environment and exposed critical gaps in organizational and decision-making infrastructures. Manual processes were challenged while the need for digital processes were highlighted. Think back to when the need to make a single product decision caused a frenzy while manual processes collapsed. The resulting negative impacts on staff morale and patient care have not been forgotten. We've learned that the value of in-person meetings have decreased while the need for dynamic connectivity has increased. Today, strategic product decisions rely on efficiently connecting the right subject-matter experts in a timely fashion to motivate defensible decision making. We are in the age of rapid connectivity at our fingertips; it is time for supply chain to board the plane and participate in the new digital landscape.

**The new normal requires alignment across people and processes in partnership with technology and evidence to operate with a clinical and strategic focus.** In essence, it is an uphill battle to increase standardization and clinical alignment without the digital processes to operationalize best practices. Organizations that haven't invested in a digital infrastructure to support decision making are at great risk of failing to meet the complex needs of the modern healthcare ecosystem. Today, the level of risk associated with decision making, the minimum threshold of data that must be considered, and the number of stakeholder groups that should be engaged all contribute to the reality that it is simply no longer feasible to approach value analysis with manual processes.



# How Can Technology Serve as a Decision-Support Tool?

## Technology supports consistency and visibility

Without an established digital infrastructure, data and processes lack continuity and are therefore vulnerable to variation in daily practice. A standardized approach requires discipline throughout the process. For example, in any product review, standard criteria should be considered during evaluation or, at minimum, be noted as non-applicable. Technology provides the infrastructure to require that all criteria are considered in order to move forward in the decision-making process. This model is operationalized by providing different questions and answers electronically to make decisions. Providing clarifying questions, sharing product information, and even voting is executed digitally. In doing so, technology serves as a decision support tool by supporting the ability to protect and execute on what is best practice, thus serving as a forcing function for standardization and governance.

For any health system, transparency is critical for collaboration and clinical alignment to occur across diverse stakeholder groups. With a digital decision-support tool, teams have the capacity to maintain an ongoing understanding of processes and make strategic decisions that recognize data across the IDN. As systems grow, reimbursements become more complex, more stakeholders are involved, and additional data points are incorporated into the decision-making process. Thus, operating with different data and processes is no longer feasible. However, standard spreadsheets and email have not evolved to serve as the dynamic centralized body that is required to successfully function today. Within a cloud-based system, stakeholders have one source of truth to defend during decision making and to reinforce standard processes. As a result, backlogs are eliminated, product requests are never buried, and data maintains its integrity.

## Technology supports integrated, democratized data

In hospital value analysis, manual information is static data. Alternatively, data stored and updated in a cloud platform has the potential to integrate consumable information for further application. For example, use, safety, outcomes, financial, and historical data are all required to make strategic, evidence-based decisions—but are static data points until a digital tool integrates them and facilitates an efficient discovery of the full value picture. Ultimately, the holistic consideration of consumable information is required to make a defensible product decision that aligns with the common goal of elevating patient outcomes. Without a decision-support tool, however, information can't be fully leveraged to support an understanding of historical data while ensuring that the latest, most relevant data is being considered.

Not only is integrated data actionable, it also allows for data democratization, where information is accessible across diverse stakeholders and serves as the foundation for a successful decision-making framework. Without a standard way for stakeholder groups to share and access data, there isn't a shared responsibility for risk management, and therefore clinical alignment is prohibited. Ongoing education and transparent data are both required in the mission of transforming a PPI-focused standard into an outcomes-focused one. Ultimately, a new standard of data sharing must be in place from both an infrastructure and a process perspective. In this mission, data-sharing should not be a one-sided process. Both physicians and value analysis professionals must support decision making and evaluation processes with defensible data, centering diverse stakeholders around a common goal. With this approach, a dependence on data becomes standard practice rather than a special request. Unfortunately, the majority of hospitals don't experience the benefits of integrated, democratized data because this level of visibility is impossible when using manual processes, where information is incomplete and siloed to specific subsets of user groups. This risk of disconnection is increasing in severity for growing networks that continue to operate without a strong software infrastructure for new product management. When this is the reality, data is gathered and stored through manual processes and therefore fails to serve as the foundation for evidence-based decision making. The use of a software solution provides health systems with a decision support tool to elevate the role of data in product evaluation. However, many supply chain stakeholders still take the comfortable route of allowing current processes to be maintained, taking precedence over the ability to realize a clinically integrated supply chain.



# Technology supports automated processes

Technology provides anywhere, anytime access to decision making, workflows, and data evaluation. Such access enables process continuity in which evidence-based decision-making is not circumstantially bound. During COVID-19, for example, the ability to meet virtually and pivot to virtual decision-making proved to be a critical need. Taking a step further, rather than manually sourcing and referring to information with one-off interactions, a digital infrastructure can partner with time-burdened stakeholders by providing one centralized, mobile-friendly place to rely on for seamlessly accessing aggregated information and standardizing engagement. Imperative in a collaborative decision-making environment, a cloud-based infrastructure has the potential to connect disparate functions, such as finance and clinical leadership, in a meaningful, convenient way. In practice, this equates to expedited decision collaboration with fewer barriers to achieving a holistic understanding of value. This state is critical because, for the great majority of value analysis and supply chain professionals, bandwidth is a significant challenge that continues to negatively impact decision-making capacity. When manual processes are replaced with digital workflows, the majority of heavy lifting is alleviated, and experts can review data at their leisure; efficiency is improved while variation is reduced. Achievement of this state also supports standardized workflows across the continuum, from initial screening and data evaluation to final decisions and future auditing activities. What is the outcome? Value analysis professionals are freed up to dedicate time to what truly matters: impacting patient care through strategic decision making.

When evaluating how a decision support technology would improve clinical alignment and support a new-world approach to value analysis, first ask, does my team:

- Maintain fully centralized, user-friendly product requests?
- Operate with an integrated, virtual stakeholder workflow?
- Have internal communication tools connected to the evaluation process?
- Have consistent support mechanisms for value analysis meetings, including virtual agendas and decision making?
- Experience high levels of physician engagement with mobile-friendly engagement tools?
- Receive critical safety data, such as FDA recall and adverse event alerts?
- Have access to and incorporate financial predictions and post-approval analytics?
- Highlight duplicate product requests for cost avoidance?
- Have the ability to quickly identify product equivalents?
- Easily compare data across products?
- Incorporate aggregated clinical research with anywhere, anytime stakeholder access?
- Have access to a clinical evidence research database with research summaries and a clinical evidence scale?

Through the standardization of decision-making and use of technology, organizations can elevate clinical alignment while improving costs, quality, and outcomes. For mature supply chain teams and health systems, that is the “why” that unifies disparate processes, focuses energies on elevating patient outcomes, and streamlines the introduction of life-saving technology into the hands of clinicians. With this framework, a subset of organizations are evolving to meet the complex challenges of the modern, value-based ecosystem. However, for those who continue to preserve the status quo with siloed, manual data and processes, supply chain disruptions, shrinking operating margins, and changing reimbursement structures will continue to threaten their viability and potential to maximally serve patients. An evolution toward the golden standard of evaluation does not take place overnight. However, elevating patient outcomes through a value-based model should always be the first priority for members of the healthcare community.

Today, executing on this standard requires a digital infrastructure for evaluation. The value analysis profession should be seen as a compass for new product introduction and clinical integration across the continuum. Ongoing change management and the prioritization of outcomes must guide the transition to a new-world value analysis infrastructure, where clinical alignment and technology serve as cornerstone partners in evidence-based decision making.



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