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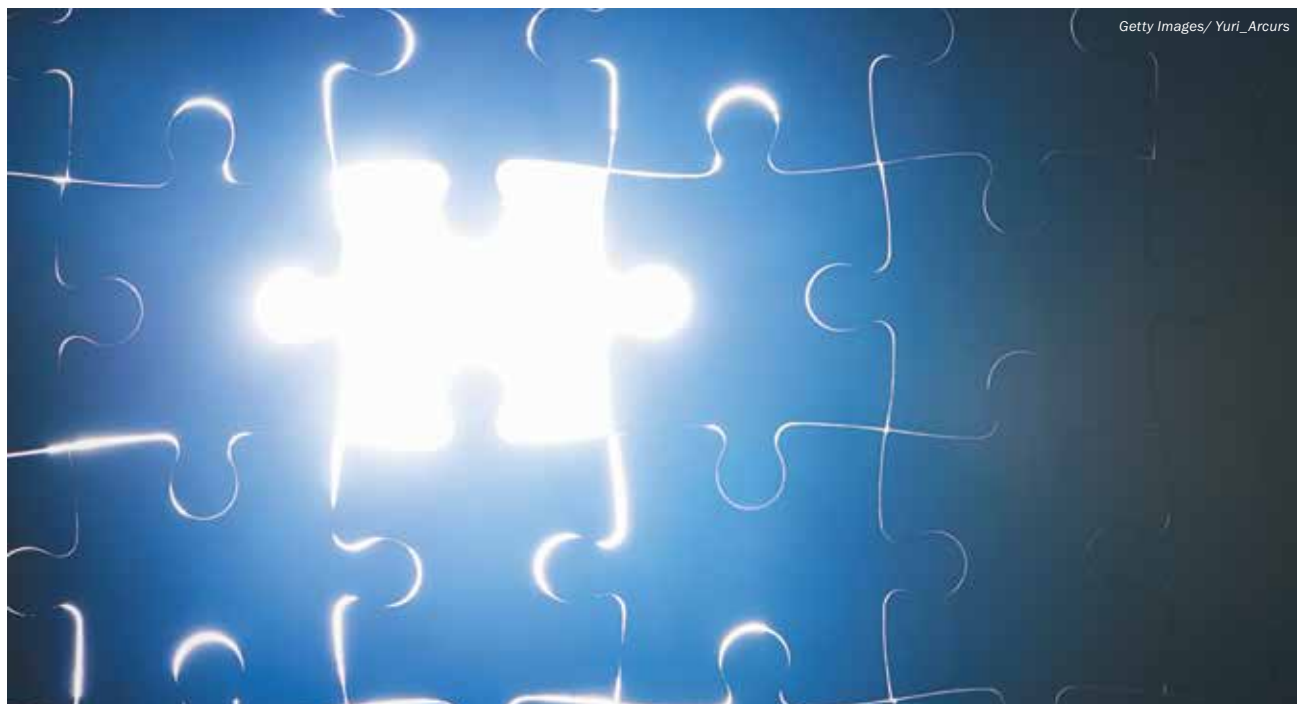
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A Star is Born

2016 BRAND OF THE YEAR

Immunotherapy Drug Blazing a Bold Path in Cancer



Pharma's Big Push for Value

A 'How-To' Primer Using End-to-End Evidence Strategies

As the shift to value-based, personalized healthcare continues, life sciences companies will need to move product conversations away from marketing-centric messages to those that highlight evidence of efficacy as well as extending the value proposition to include services "beyond the pill." To thrive in this "facts-beat-marketing-hype" future, companies must embrace a new operating model based on end-to-end (E2E) evidence management across the entire product life cycle.

By R. Terry Hisey and Brett J. Davis

The shift to outcomes- and value-based healthcare, along with more personalized therapies, is increasing the importance of end-to-end (E2E) evidence management capabilities in product development, marketing, and distribution. In the past, a value proposition was driven by marketing campaigns, claims-based messaging, and scientific sound bites. While clearly based on fact, the value proposition did not highlight the evidence dimension or, if it did, make it

central to the measurement of outcomes in the real world. The new market reality is to require empirical evidence to be positioned at the heart of the value conversation along with patient services "beyond the pill," rather than on marketing profiles and unit cost and rebate pricing strategies.

Given this shift, how should companies manage evidence differently throughout the product life cycle and across the various channels of the healthcare ecosystem? This strategy analysis examines the imperative for E2E evidence management for a "facts-beat-marketing-hype" future. Specifically, this article:

- » Discusses how E2E evidence differs from real-world evidence (RWE), advanced analytics, and big data.
- » Outlines essential elements of an E2E strategy, including operating model, partnership, and IT/informatics considerations.
- » Frames key components to becoming an insights-driven organization.
- » Explores the possible downside implications for companies that have not prioritized the imperative for an E2E evidence strategy.
- » Poses questions organizations need to be able to answer under the new evidence paradigm.

E2E evidence management: Making the case

Reimbursement in the healthcare market is shifting toward rewarding value instead of volume; this is also true for pharmaceutical interventions, as seen in an increasing number of outcomes-based contracts in the sector. As a result, life sciences organizations are adapting their product value conversations with payers and other commercial stakeholders to concentrate on evidence around product efficacy, safety, and economic value as well as offering beyond-the-pill services to deliver a more robust value proposition to their customers.

Additionally, researchers are targeting more specific disease states based on a growing understanding that patients comprise more than a mass of generic diseases and can be broken down into smaller, defined groups based on biomarkers, comorbidities, or treatment pathways. To succeed, these new approaches

Evidence is now at the core of decision-making—and a strong evidence base will produce more productive conversations with customers and other healthcare stakeholders

to drug development require a greater volume and variety of evidence.

To mark an effective response to these changes, pharma companies should consider an E2E evidence management strategy (see Figure 1 on page 32) as one of the key ingredients to identify targeted breakthrough innovations, rapidly get the new products through development, and successfully launch and market them in a value-based care environment.

An E2E strategy will assist organizations in becoming more insights-driven so that decision-makers can act on the basis of rigorous, data-based insights rather than general strategy. Implementing processes to capture and analyze data and to leverage and apply that data for meaningful and sustainable results is a necessity, for a number of reasons: these processes result in better data transparency and utilization; provide increased availability of insights

to a wider group of people; facilitate less expensive, targeted clinical trials; accelerate product approvals; enable on-target market access strategies; create comprehensive, real-world effectiveness analyses; and help to support new customer engagement models. Ultimately, in the new health ecosystem, evidence is at the core of decision-making, and a strong evidence base will produce more productive conversations with customers and other healthcare stakeholders.

In Figure 1, we divide the E2E evidence value chain into three components: discovering value, generating value, and optimizing value. During the drug development process, companies should first make portfolio decisions by “discovering value” through clinical trials, then move to “generating value” through product approvals and compliance and, ultimately, “optimizing value” through commercialization and market access.

FAST FOCUS

» An insights-driven model such as end-to-end (E2E) evidence management is a necessary operating strategy in pharma today. Advantages include better data transparency; the design of less expensive, targeted clinical trials; the acceleration of product approvals; more on-target market-access channels; and the creation of comprehensive and real-world effectiveness analyses.

» A strong evidence strategy must be cyclical—the evidence used to optimize product value should be filtered back to inform new opportunities for therapeutic discovery and development. Conversely, data and insights generated from the early part of a product’s evidence life cycle should be leveraged to modify and anticipate shifts in market behavior in the commercial setting.

» Becoming a true insights-driven company and executing E2E evidence management in daily practice requires alignment across the key components of strategy, people, process, data, and technology.

End-to-End Evidence Generation & Management



Figure 1. Source: Deloitte

During early-stage research, evidence management can help an organization discover value by enhancing pre-clinical and clinical research productivity through precise target and patient cohort identification. As concepts mature into products, evidence management may enable an organization to generate value and maximize a product's potential for clinical and commercial success by leveraging traditional clinical trial data and RWE to segment patient populations for optimal therapeutic response and safety. Finally, when therapeutic interventions are approved and launched, companies can optimize their value by assessing market dynamics to support pricing and market access strategies, and by applying RWE to develop, support, and sustain a compelling value story as the products are utilized in a healthcare environment.

A strong evidence strategy is cyclical, so the evidence used to optimize product value should also be filtered back to inform

new opportunities for therapeutic discovery and development. Conversely, the pace and disruption of scientific innovation also means that data and insights from the early part of the evidence life cycle should be rapidly leveraged to modify and anticipate shifts in market behavior.

E2E evidence strategies and capabilities are no longer a “nice to have;” they are a necessary business component to develop, launch, and sustain successful products. Therefore, the imperative for new E2E evidence strategies and capabilities has implications for technology investments, organizational constructs, and new business models, including external partnerships.

What are the essential elements of an E2E evidence management strategy?

Developing and implementing an E2E evidence management strategy requires a level of organizational maturity and insight to move beyond the traditional view of product life cycle man-

agement, break down the resulting silos, and incorporate important functions such as strategy, governance, external collaborations, new informatics approaches, and talent management. Evidence management also calls for reducing or eliminating the walls around patient data throughout the R&D process by establishing new platforms that enable end-to-end views of data and analytics centers of excellence to support the new paradigm.

Effective evidence management can help to shave off cycle time and dollars from the product development process by informing clinical trial protocol development, thus helping to justify a company's investment in a certain asset that could impact a new disease area or, conversely, supporting the decision to forego development of a particular product because the evidence indicates low potential for economic success. In addition, an E2E strategy can help increase on-patent revenue generation and keep organizations competitive by being “first to market” and thus contribute to return on investment.

The essential components of an E2E strategy can vary by organization—and are likely to involve and impact people, processes, and technology across multiple internal and external touch points. Determining specific needs calls for an assessment of core capabilities such as infrastructure, governance, talent, R&D, and commercialization.

A few essential elements are necessary across all organizations for an effective E2E evidence strategy:

- » Top-down sponsorship and enterprise-wide alignment.

- » Broad understanding of the necessary changes to the organization's business and operating model.
- » A plan for external collaborations to support the new business and operating model.
- » Next-generation IT and informatics infrastructure and human capital to support the new model.

How can an E2E evidence management strategy support an insights-driven organization?

Often, R&D and market strategies are driven by a new technology innovation (e.g., cognitive computing) or a promising data type (e.g., genomics, social media). However, the journey to becoming an insights-driven organization and achieving the promise of E2E evidence management requires alignment and execution across the key components of strategy, people, process, data, and technology (see Figure 2).

Some of the questions organizations need to answer about these components include:

- » **Strategy:** For the patient populations we serve, how will changing science, reimbursement models, and patient behavior impact the need for generating evidence to inform product design, patient care, and overall business decisions?
- » **People:** Do we have the right talent to make sense of the new types of healthcare information available to us? Who is the accountable business owner for this information? What organizational structure do we need to put in place to support our analytical strategy? Who do we need to engage in other departments and what are

Journey to Becoming an Insights-Driven Organization



Figure 2. Source: Deloitte

their roles? What other talents do we need and what is the plan for acquiring them? What competencies should we source from external partners?

- » **Process:** How do we ensure that insights are shared across traditional organizational silos? What are the steps we need to take to make these projects a success? How will we comply with relevant regulations? How do we fund and measure the impact of these investments and new operating models?
- » **Data:** What data do we need to answer today's questions? How do we source data through novel collaborations that our competitors can't access easily? How do we bring data together and what are the challenges in transforming, linking, and publishing it? How can we improve data quality and accuracy?
- » **Technology:** What technology architecture supports the new needs of expanding sets of data? What tools do we need to process the evidence? What security

measures do we need to consider in federated models of data collaboration? How do we scale up the technology when we need to roll out our solution to the rest of the business?

The process of implementing an E2E evidence management strategy may be complex, and time- and resource-intensive, but the innovation, efficiency, and commercial benefits may help to justify the investment. Moreover, with the right insights, E2E evidence can become a major source of competitive differentiation.

Using evidence across the development life cycle: Five hurdles

There are five dimensions of complexity that may make it difficult for life sciences companies to successfully execute an E2E evidence management strategy: disease state complexity, domain or functional complexities, geography, regulations/reimbursement, and operations (See Figure 3 on page 34). Each category has implications for a company's business strategy, operating

Evidence: The 5 Dimensions of Complexity

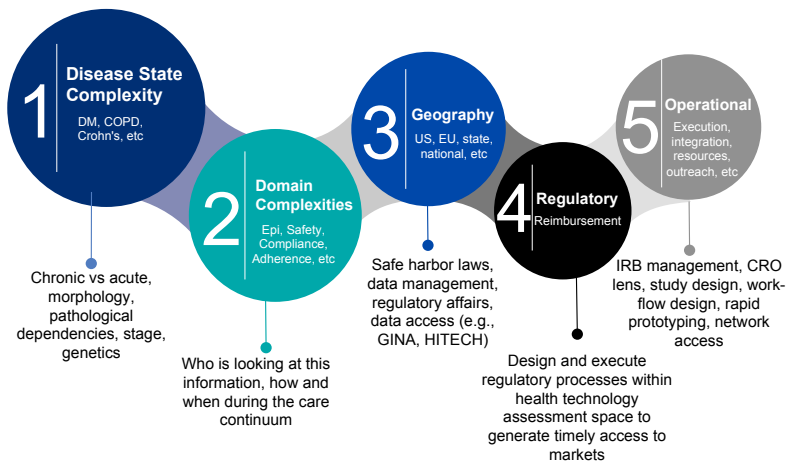


Figure 3. Source: Deloitte

model, and requisite IT and informatics platforms.

Disease state complexity:

Understanding and mapping the patient journey for a chronic disease such as diabetes requires different data sources, data sets, informatics approaches, and external collaborations than the patient journey for a rare cancer. As the scientific understanding around a disease evolves, changing definitions, dependencies, or new classifications can result in data and informatics challenges as well as talent and training implications.

Domain complexity: Exacerbating disease state complexity is the fact that an E2E strategy touches every functional domain group in the product life cycle. This means that the design and implementation of every process—from the way partnerships are established, to regulatory compliance, to how third-party data sets are procured—will need to consider the specific needs of the functional groups that will use the data sets.

Geography: Evidence gathering, management, and measure-

ment requirements can vary dramatically by geography. For example, the health technology assessment (HTA) process in many European countries has different evidence requirements than the process for US health plans and pharmacy benefits managers (PBMs). Additionally, data analytics have uncovered major differences in care patterns across and even within countries.

Regulatory: Health information is highly regulated by local governing agencies. Researchers cannot always use health information for secondary research, transport data outside local borders, or approve a product without local research samples. Even when it can be transported and aggregated for analytical purposes, the integration and semantic challenges inherent in healthcare information can present regulatory complications around its use and analysis.

Operational: Operational considerations include the ability to integrate data sets and understand the appropriate resources for the necessary analytics as well as tactical issues around

data quality and data access. If the necessary problem-solving capabilities do not reside within the organization, an external partner may provide valuable support. This can impact technology infrastructure and external partnerships.

The combination of these five dimensions of complexity and inherent IT and informatics challenges negates a one-size-fits-all approach to developing and successfully executing E2E evidence management. Rather, the process is multi-dimensional and requires an enterprise-wide strategy, operating plan, informatics and data platforms, and cultural shift.

The slow pace of fast disruption

Some life sciences companies may choose to opt out of an aggressive, E2E evidence management strategy, citing that similar assertions about disruption have been overstated in the past. By doing so, they may face risks, including poor decision-making around capital and asset allocations, a less efficient product life cycle, and failure to realize a product's full market potential and, possibly, the opportunity to develop the next life-saving medical treatment. This is true because of the perfect storm of reimbursement changes, scientific advancements, significant cost and quality pressures on healthcare, the proliferation of healthcare information, and the IT advancements (security, cloud computing, big data, analytics) that make pursuing such a strategy feasible. As a result, E2E evidence management is becoming a core business capability—companies that are unable or unwilling to embrace this new paradigm may experi-

ence significant disruption and bottom-line impacts.

Leveraging data to demonstrate value: Questions to guide your strategy

An E2E evidence management strategy provides a cohesive approach to leveraging data in

new ways to rapidly translate breakthroughs into clinical practice as well as demonstrate and understand the value of those innovations in real-world settings. The following questions may be important for an organization to ask in order to start the journey to an E2E evidence strategy:

- » What decisions require an evidence management strategy?
- » Do we have a common definition and accepted metrics for “evidence” or are they part of the challenge to developing a strategy?
- » Which functions rely on evidence most to drive decision-making?
- » How do we leverage evidence across all product development, marketing, and distribution channels?
- » What components (capabilities, technologies, etc.) are essential to successfully implement and sustain this strategy?
- » What impacts will this strategy have on internal operations, governance/regulatory, compliance, commercialization, data systems, vendor and customer relationships?
- » What is the appropriate funding allocation for an evidence strategy?
- » What are the implications of moving or not moving forward with an E2E evidence management strategy?

Comparing E2E Evidence and RWE

It is important to note that end-to-end (E2E) evidence management and real-world evidence (RWE) are complementary—but different. E2E management encompasses RWE but is a broader concept. If RWE is not understood and applied under this construct, it risks becoming yet another data silo in a biopharmaceutical enterprise.

RWE has emerged as a broad and powerful capability with the potential to improve drug development and the product approval process. Randomized clinical trials are and will continue to be the gold standard of evidence; however, their growing costs, lengthy time commitments, and lack of generalizability have prompted researchers to expand their scope of evidence.

RWE encompasses any data outside clinical trials, including evolving technologies such as mobile devices and sensors. Despite the acknowledged use case for RWE in product development and authorization—RWE can improve market understanding of a product and better enable life sciences companies to compete on value—its full potential is often unrealized due to organizational complexity, fragmented tools, lack of data integration, and gaps in capabilities and expertise; in essence, the absence of an end-to-end vision for evidence management. RWE is a vital component of an E2E strategy but it remains just one piece in the overall mission to democratize evidence.

E2E evidence is a more expansive

concept than RWE; for example, across the dimensions of data type and data application. With an E2E evidence strategy, the goal is to create a near-real time, data-driven view of a disease inclusive of the complexities of real-world populations. This means considering data types ranging from genomics through post-launch (i.e., RWE). In addition, the application of E2E evidence transcends the “silos” of the traditional pharmaceutical value chain. For instance, leaders in E2E evidence management are applying real-world data insights to early R&D decision-making as well as creating operating models and data systems that enable scientific insights driven out of R&D and externally to be crafted into dynamic value propositions for the market.

Finally, an E2E evidence strategy and operating model recognizes the increasing importance of external collaborators and new business models centered on data. For example, patient advocacy groups are increasingly creating linked data networks across multiple healthcare systems. These networks are generating new longitudinal data sets that can lead to insights about the optimal use of therapies in complex populations and identify opportunities for discoveries around unmet needs. Teaming with these types of groups as well as harnessing the power of patient data being generated elsewhere in the healthcare ecosystem will be critical in an E2E evidence-based world.

Staying the course

The life sciences industry and larger healthcare ecosystem are constantly adapting to better meet the needs of patient health and well-being. This article presents a moment-in-time snapshot to illustrate a “good” place to be in the evidence management space; but, like the industry itself, the concept of “good” will evolve.

As technology, regulatory compliance, and market demands change, so will a company’s evidence strategy; therefore, that strategy should always include elements of continuous learning and continuous improvement. **PE**



TERRY HISEY is a Principal, Life Sciences and Health Care, at Deloitte Consulting LLP. He can be reached at rhisey@deloitte.com



BRETT J. DAVIS is a Principal, Life Sciences and Health Care, at Deloitte Consulting LLP. He can be reached at brettdavis@deloitte.com