FierceLive! WEBINARS

End-to-End Evidence Management Can Enable Value-Based, Personalized Healthcare.

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End-to-End Evidence Management Can Enable Value-Based, Personalized Health Care

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Speakers

Terry Hisey

Principal, Deloitte LLP

Life Science and Health Care

rhisey@deloitte.com

Mary Cummins

Principal, Deloitte LLP

Life Science and Health Care

mcummins@deloitte.com

Discussion Areas

- How's the overall health care sector changing and what kind of new reality does this create for Life Sciences?
- What is needed in a fact based shift to value future?
- Biopharma's industry response with evidence.
- How are different stakeholders thinking and acting around evidence?
- What are key questions stakeholders need to answer and act on?

We are in an unprecedented period of change in the heath care ecosystem

Increased scrutiny on “value” in the US as those financing health care seek new alternatives to deal with unsustainable cost burden and relatively poor ROI on per capita health spend; continuing pressure globally

New Health System Payment Models

A **wide range of payment models** is now in use between payers and providers, changing their fundamental businesses and behaviors

- Providers funded via Traditional Fee for Service through Shared Savings, Shared Risk and through to Global Capitation; growing traction for Bundled Payments

Stakeholders Changing

Life Sciences companies must now engage a **new set of decision makers and stakeholders**

- Consolidating providers and payers, providers with their own plans, physicians employed by hospital systems, new influencers …

Increasing Evidence Demands

Growing demand for **new forms of evidence** from variety of stakeholders (Government, payers, providers, etc.)

Intensifying Public Scrutiny

… And the value debate is being amplified as biopharma companies come under scrutiny for **pricing and affordability**

Payers and providers are under intense pressure to redefine their businesses in search of sustainable profitability and growth – the default discussion with Life Sciences manufacturers becomes cost as a proxy for value

Health care providers are living in a “New Normal” with a focus on value rather than volume

The evolution of the U.S. health system from volume- to value-based care (VBC) is under way, spurred by widespread efforts to control/ reduce costs, improve outcomes, and obtain more value for money spent.

Organizations are increasingly focused on population health and how they can drive improved outcomes through value based care delivery models

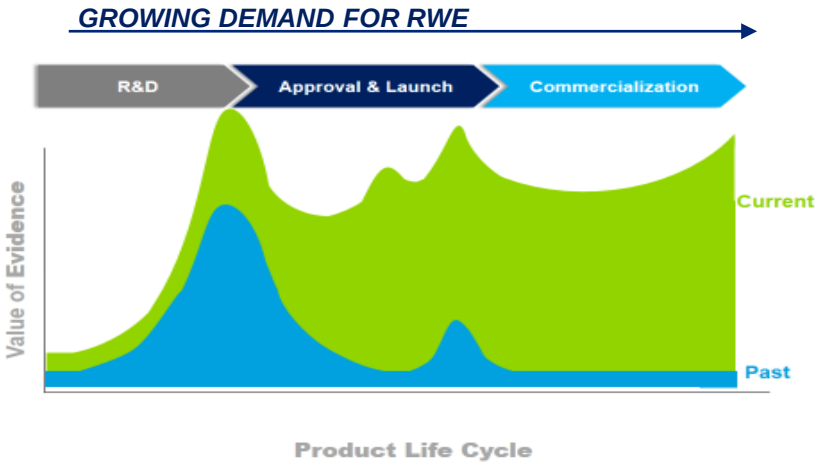
This “New Normal” has significant implications for life science companies

	From…	…To
Influencers	Fragmented providers, payers, and pharma	Consolidation among existing stakeholders, emergence of new influencers
Decision-Making & Purchasing	Individually-led, focused on unit cost	Highly centralized, guideline-driven, focused on rationalization for both cost and consistent outcomes, managing utilization and alternative care delivery
Getting Paid	Volume-based	Outcomes-based, focus on risk sharing, new episodic models taking hold
Standardization and Transparency	Limited visibility across organizations, limited metrics tracking	Metrics tracking quality, outcomes; increased pricing transparency
Patient Centricity	Direct to consumer marketing to engage patients	Increased emphasis on data-driven continuous improvement of patient experience
Data Requirements	Product value based on clinical trial data and as needed real world studies	Fundamental need for new kinds of data, recognition that same data will be used differently by different groups (internally and externally)

In order to prove value and articulate their value proposition, companies will need a strong evidence lifecycle management capability

The imperative to leverage evidence throughout the product life cycle is driving change to business processes

- Real World Evidence (**RWE**) has emerged as a **powerful and broad based capability** to shape and inform the shift to value based, personalized health care.
- What began as comparative research and outcomes research has matured into an ever expanding framework of data and analytic capabilities to **enable more accurate and more efficient health care and health product decision making.**



Changing RWE models within the LS industry

RWE Mandate	IT & Informatics	Source of Data and Tools	Value Creation
From observing and understanding…	*From tightly coupled data and analytics solutions for technical "experts"…*	*From data providers seen as vendors and suppliers…*	*From evidence generation primarily supports commercial objectives…*
…to shaping and Influencing	*…to standards based, modular architectures that empower domain experts*	*…to data providers seen as partners and collaborators*	*…to evidence informing product design and patient care*

The move to new evidence strategies and capabilities has implications for technology investments, organizational constructs, and new business models.

The effective use of real world data and evidence can help revolutionize the life sciences industry…

…But in order to advance the use of data and evidence, organizations must overcome many challenges

Operational Complexities

Exponential growth in volume of data:

- Crushing infrastructure
- Outdated solutions
- Processing bottlenecks
- Cost pressures
- Burden to manage
- Complex to secure

New types of data compounding challenges:

- Social, mobile
- Real world data (claims, EMR, survey)
- Clinical trials
- Genomics
- Post marketing safety surveillance

Dependency on historical reporting & manual heroics:

- Slow, inefficient
- Insufficient granularity
- Siloed solutions
- Incomplete views
- Lack business drivers
- Talent pressures

Decisions & actions constrained by insights available:

- Missing, too late
- Hands of few
- Back end of the process
- Slow to implement
- Opportunity costs
- Competitive threats

Strategic Considerations


Operating costs


Risk reduction


Data & Information Assets


Competitive threats


Changing industry boundaries


Regulatory demands & compliance


Global

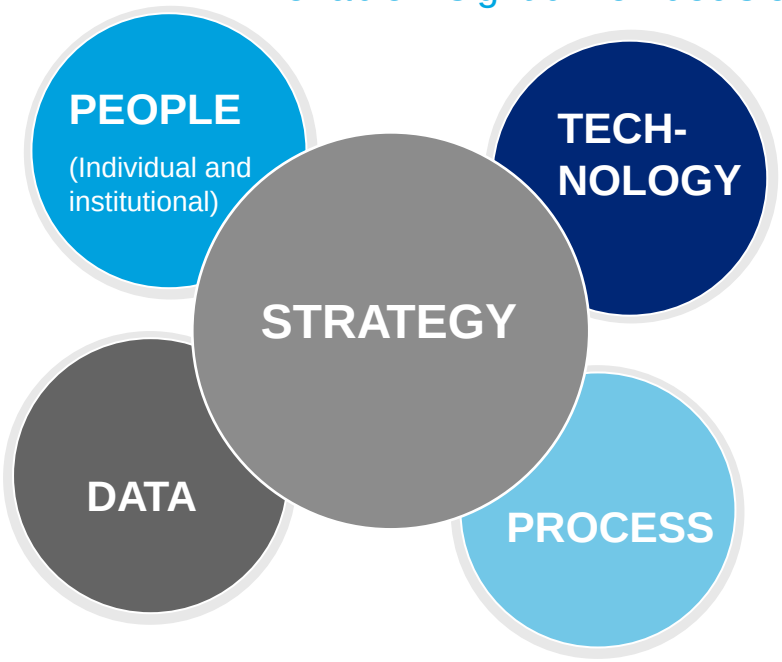

Talent

Evidence Life Cycle Management (ELM) and why is it important?

Throughout life sciences organizations, data and evidence are generated and used for various purposes. Historically, this information is **underutilized** due to organizational structure, culture and lack of technology. Because of this, opportunities are missed to realize the full value this information brings to an organization and the many decisions that are made on a daily basis.

What is Evidence life cycle management?

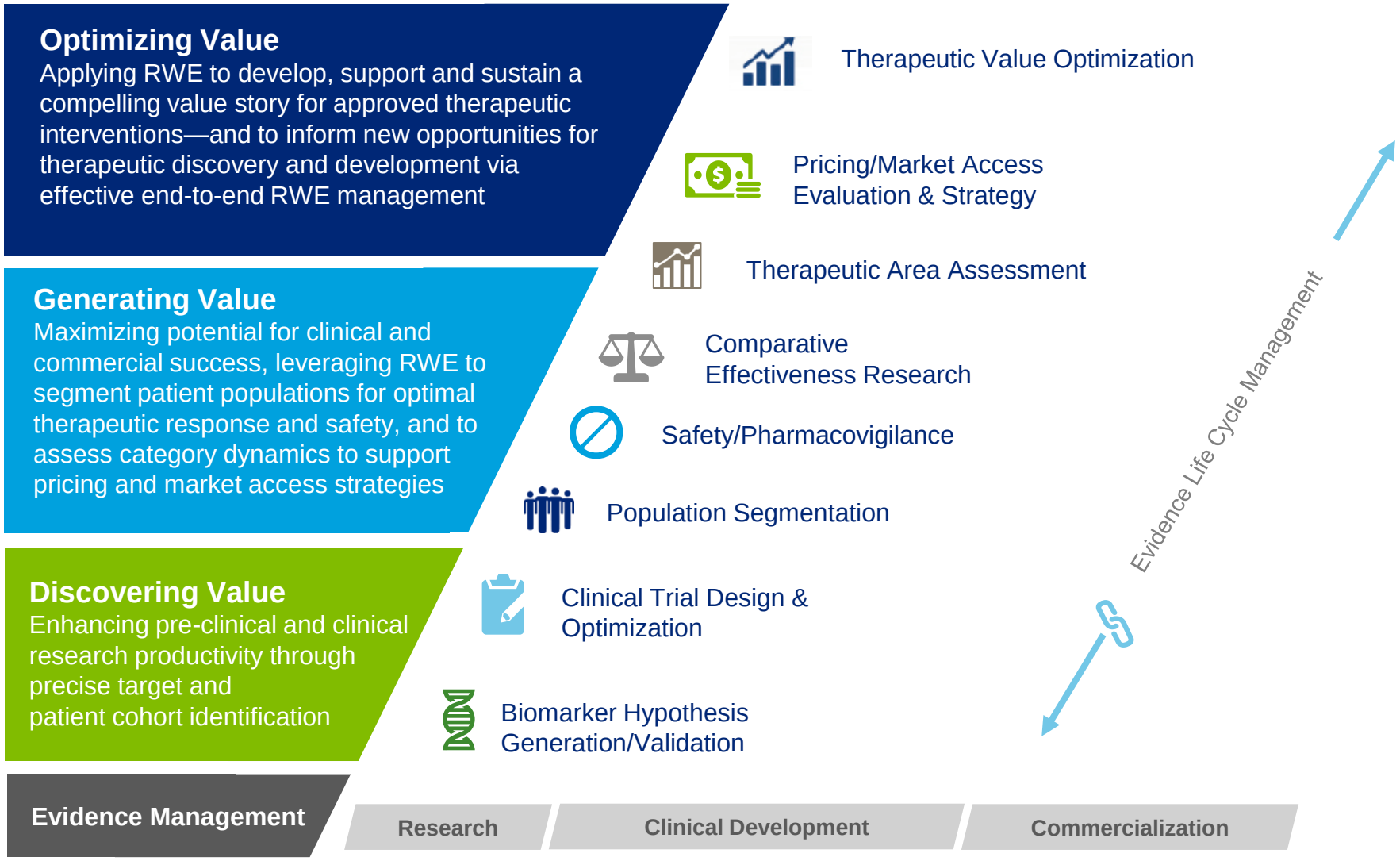
An end-to-end approach to leveraging the data, evidence, and knowledge assets of a life sciences organization that breaks down traditional siloes that exist and enable insight driven decision making from R&D through commercialization.



End to End Evidence Management is an enterprise wide strategy with implications across the organization

As health care shifts to a value-based model
ELM will play a vital role in the success of life sciences companies

An ‘End-to-End Evidence Management’ approach enables the integration of evidence driven insights and knowledge across the organization



Evidence has multiple complex dimensions that must be considered in an end-to-end evidence strategy

Domain Complexity

Various functions are solving for different questions and have different data needs

Geographic

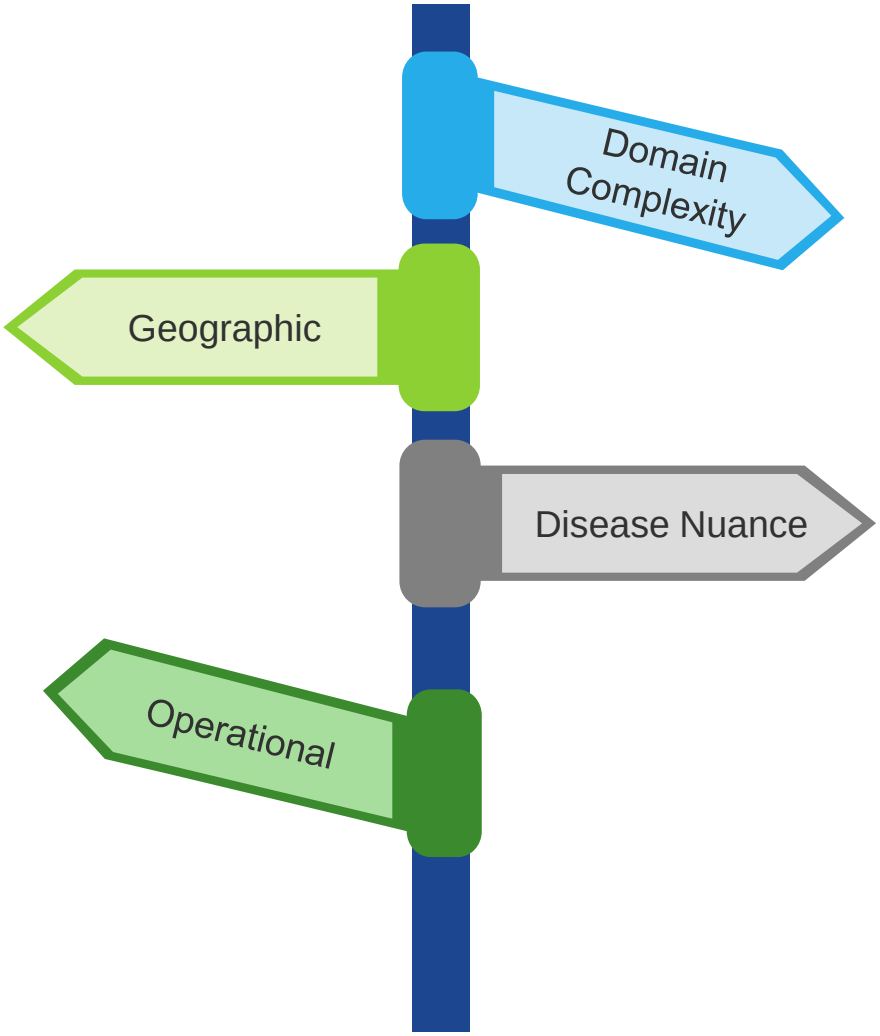
Discrepancies and differing needs in breadth and depth of data coverage

Disease Nuance

Treatment dynamics and patient profiles unique to each disease state

Operational

Execution, integration, resources, and outreach challenges

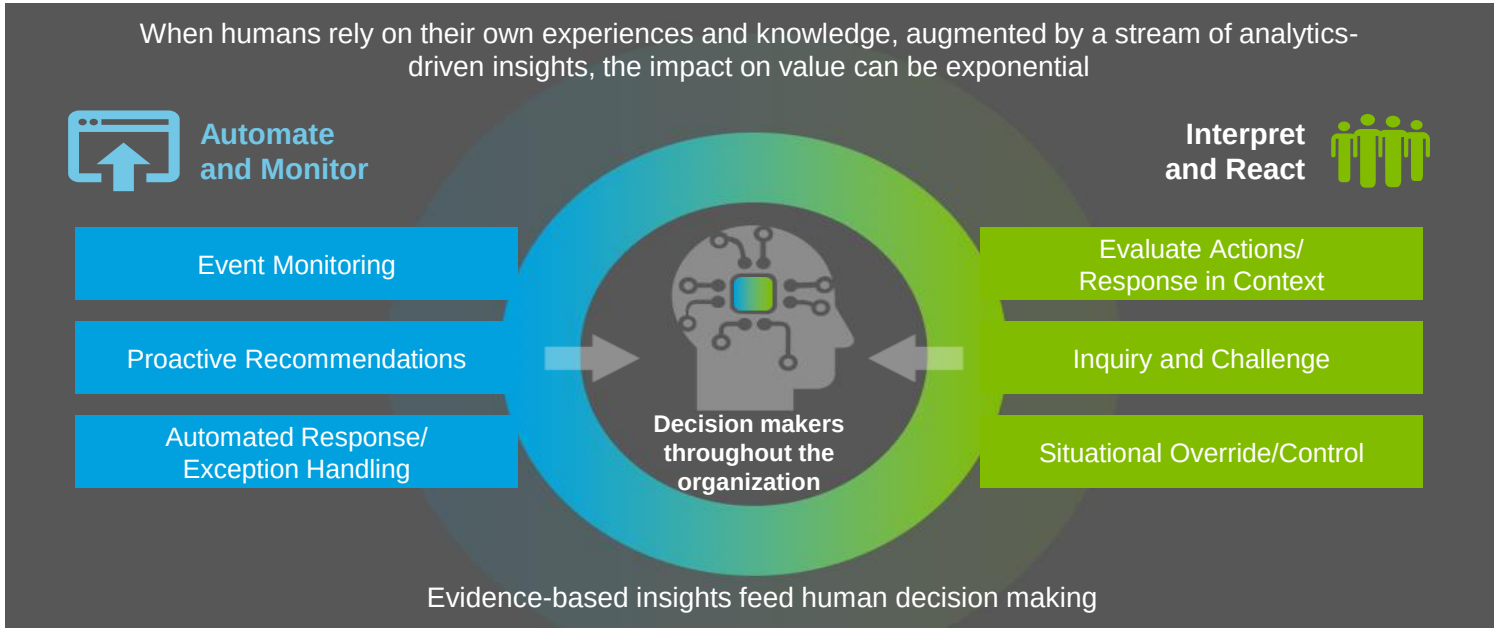


There is a fundamental need for new kinds of data and evidence, but also an understanding that these will be used differently by various groups

An evidence strategy is no longer being considered optional, rather integral to the success of any therapeutic pipeline. But the strategy and governance around managing these sources across functions is becoming challenging.

In order to compete in the evolving health care landscape, life science organizations must become increasingly “insight driven”

An Insight-Driven Organization (IDO) is one which embeds analysis, evidence, and reasoning into the decision-making process. An IDO sees analytics as a core capability embedded across the organization – from strategic planners through line workers – providing insight at the point of action and supporting decision-making at the right place and the right time.



Impact

- **Improve the speed of decision-making**
- **Make better decisions**
- **Decrease the cost of decision-making**
- **Become more innovative**

E2E evidence management is a strategic business capability that can help enable innovation, efficiency, and commercial benefits of a business. It is best conceived by asking and answering a set of “interdependent questions” to arrive at the right decisions and commitments:

Do people and organizations have the level of “Evidence Intelligence” to drive value

What impacts will this strategy have on internal operations, governance/regulatory, compliance, commercialization, data systems, vendor and customer relationships?

Are we configured in a way to delivery optimal evidence capabilities?

What is the appropriate funding allocation for an evidence strategy?

What investments or collaboration do we need to invest in to build capability?

What are the implications of moving forward or not moving forward with an E2E evidence management strategy?

How do we leverage evidence across all product development, marketing, and distribution channels?

How do various functions rely on evidence to drive insight decision-making?

What components (capabilities, technologies, etc.) are essential to successfully implement and sustain this strategy?

Do we have a common definition and accepted metrics for “evidence” or are they part of the challenge to developing a strategy?

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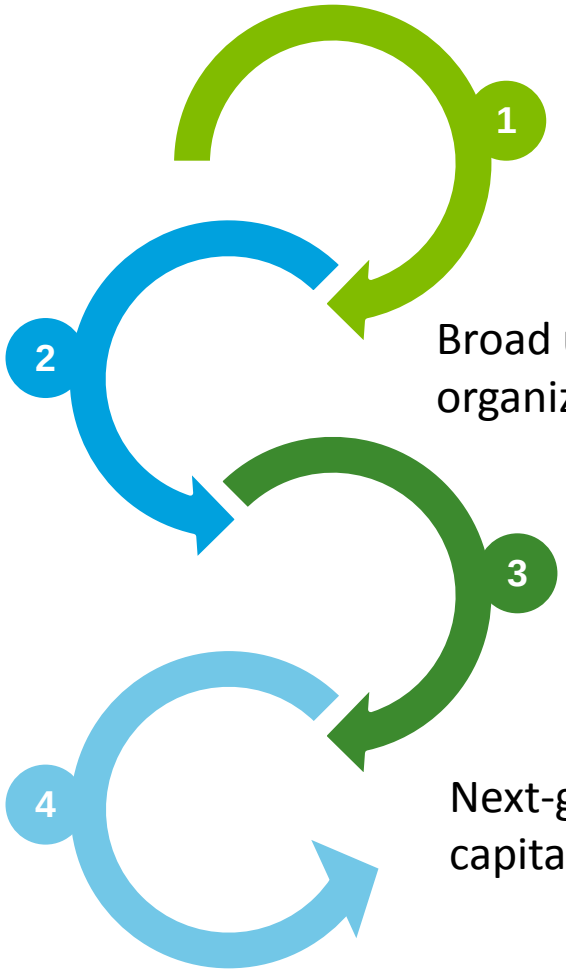
A few essential elements are necessary across all organizations for an effective E2E evidence strategy



1. Clear, top-down sponsorship and enterprise-wide alignment
2. Broad understanding of the necessary changes to the organization's business and operating model
3. A plan for external collaborations to support the new business and operating model
4. Next-generation IT and informatics infrastructure and human capital to support the new model

Thank You

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