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Life sciences companies:

Patients have a lot to say about your products. Are you listening?

"The font on the packaging is too hard to read." "The dosage instructions just weren't clear." "I couldn't get the package open, and when I did, I ripped the instructions."

These are just a few examples of the types of patient insights that life sciences companies have traditionally found challenging to mine. But now, using the power of AI, that is changing. In the Age of With™, companies can look beyond traditional applications of adverse events, complaints and other product information to generate deeper patient insights, improve the patient experience and deliver stronger outcomes.

Life sciences companies have access to a vast amount of patient and health care provider (HCP) data to meet regulatory compliance and operational needs. Yet many organizations are underutilizing these rich and valuable datasets, failing to extract actionable insights that can fuel product development and sustain competitive advantage. In many cases, organizations make considerable investments in market research and various third-party data providers but fail to capture the value of free information stemming directly from the patient or HCP (e.g., adverse events, product quality complaints).

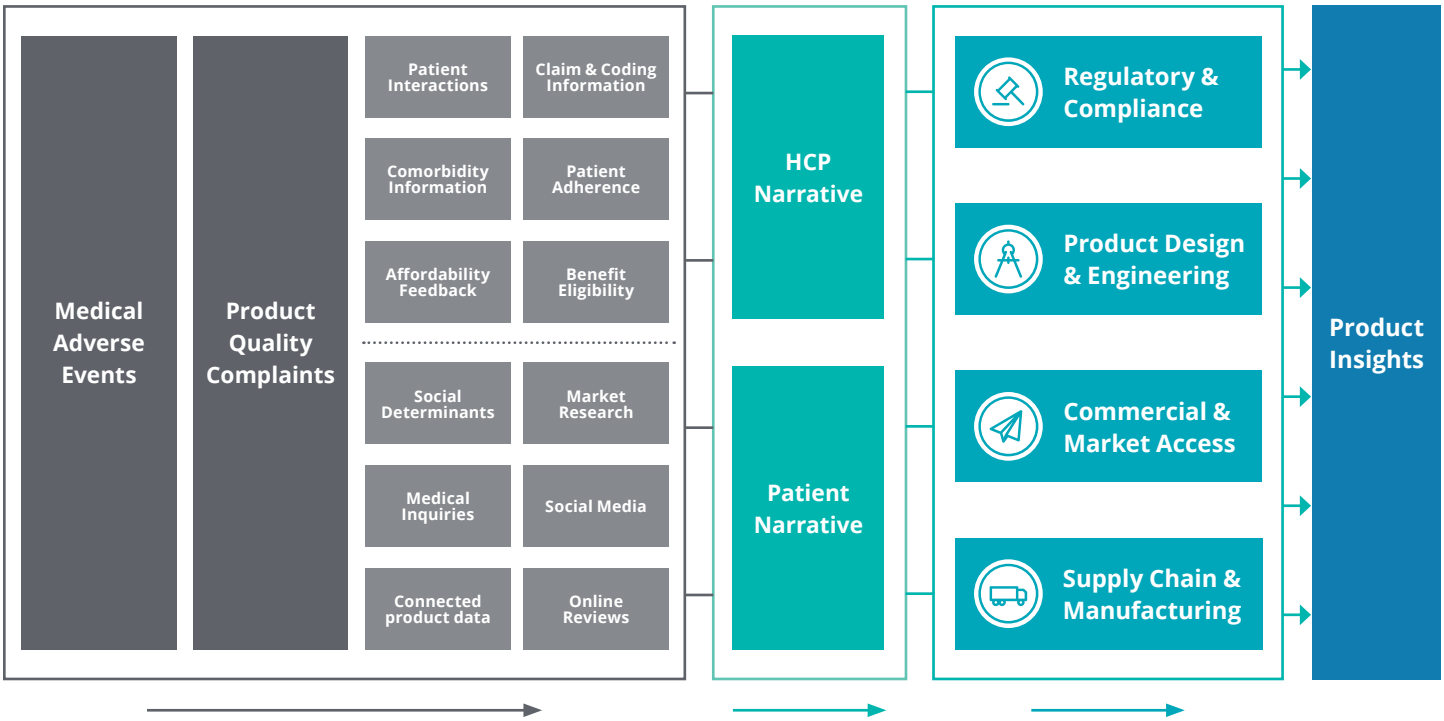
Deloitte's work with leading biopharmaceutical (biopharma) and medical technology (medtech) companies has uncovered several roadblocks to leveraging unstructured and structured data at the enterprise level. When product development involves more than a dozen handshakes—from design to manufacturing to delivery and usage—compiling and mining data at every node to obtain intelligent information can take weeks and months. Reasons include:

- **Product data complexity:** Unstructured text (e.g., narratives such as free-form text, images, PDFs, descriptions of issues) is complex, lengthy and, potentially, biased. The data can come in multiple formats, requiring significant transformation and lacking interoperability.
- **Extensive manual effort:** Customer inquiries and complaints processing are laborious, and require human interventions to monitor multiple systems, analyze data, and drive insights.
- **Focus on operations:** Companies focus on meeting operational goals in a siloed functional manner and fail to address larger strategic objectives, which usually require cross-functional engagement and alignment.

Now, with the help of artificial intelligence (AI), companies can clear these roadblocks. AI enables life sciences companies to collect and aggregate product-related voice-of-the-patient data from internal and external sources—social media feedback, complaints, adverse events, and more—and generate actionable insights that can improve product design, packaging, and educational materials.

AI and machine learning (ML) capabilities organize and comingle structured and unstructured product data from patients, HCPs, social media, supply chain systems, and other sources to uncover hidden patterns. AI/ML drives holistic product intelligence by mining patient and HCP narratives to identify trends, issues (e.g., product quality complaints), root causes, and opportunities for iterative improvement (figure 1).

Figure 1. AI/ML capabilities unlock insights and break down enterprise silos to drive holistic product insights



Core business function owners can use the resulting insights and recommendations to meet their specific needs (figure 2).

Figure 2. Product insights generated through AI can support several functional objectives

Business function	Example strategic objectives	AI-generated insights help executives
Product Design *Creates design and development specifications for new products, incorporating innovative materials*	• What are my customer unmet needs that can be addressed in the future product release? • How can I improve the HCP experience in the operating rooms?	Better understand **user behaviors** and receive recommendations **tied to product specifications**, which can be applied to future designs of similar products
Manufacturing & Supply Chain *Manages end-to-end supply chain & manufacturing operations to drive predictable, reliable supply of products*	• How can I segment my suppliers with minimal product issues? • How can I more accurately forecast demand based on external social factors?	Have **greater visibility** into the root cause of operational and logistical issues driving patient and HCP dissatisfaction, with the ability to **drill down** by process/ product
Quality & Compliance *Serves as the primary driver of quality complaints and CAPA investigations and maintains agility in meeting regulatory requirements and risk-sensing product recalls*	• How can I reduce adverse events and recalls? • How can I reduce the overall cost of quality and compliance?	**Accelerate** investigation time for quality complaints and adverse events, with the ability to **pinpoint** errors at the batch level and improve compliance review processes
Commercial Operations *Focuses on improving product performance through effective engagement with patients and HCPs*	• What is driving decreased product sales and negative patient & HCP perception? • How can I incorporate patient & HCP feedback into future product launches?	Better understand the **sentiment and trigger words** driving negative perceptions of products and estimate the **revenue impact** of addressing "voice of the market" feedback

AI helps transform data-driven decision making from "we think" into "we know" by creating a holistic, patient-centric feedback loop that enables companies to achieve next-level efficiencies, improved time to market, enhanced value, and quality within product development.

Deloitte analyses have quantified the potential value of applying AI-generated product intelligence to regulatory investigation and product iteration processes: Based on the average time to close a product complaint, AI-improved product intelligence could reduce the life sciences regulatory investigation process by 55-60 percent. Based on the percentage of complaints in which patients talk about switching to a different medication due to product ineffectiveness, copayment assistant program issues, and unclear use instructions, incorporating voice-of-the-patient insights into product iterations could help increase a life sciences company's market share.

A recent Deloitte project illustrates AI in action. A life sciences company's combination products were underperforming in the market. We prototyped and implemented a solution to uncover insights and create a patient-centric feedback loop. Through AI we:

- Aggregated product quality complaints and medical adverse events across disparate sources to create a singular voice-of-the-patient index
- Analyzed complaint text using natural language processing (NLP) algorithms, identified "missed dose" as a frequent issue, and determined that patients perceived the product as ineffective or not able to address the disease
- Comingled patient complaints with product specifications to deduce that there was a product design issue and pinpointed the root cause in specific components of the product
- Provided drill-down data and insights to the product owner, initiating action to address the issue with the product development, quality, regulatory, and medical affairs teams.

Based on this intelligence, the company gathered valuable insights which will be used in development of the next generation of the product, designed with a more intuitive syringe system and simpler user instructions. In addition, the company was able to leverage insights gained to inform design and development of other injector products, resulting in development of a common product platform across all injection devices.

Future state: A product-centric, continuous feedback loop

AI will enable a fundamental shift in product development, transforming linear processes with ad hoc, time-consuming tasks and fixes to a cyclical feedback loop with iterative processes that enable a stronger focus on patient/customer perspectives.

Life sciences companies looking to implement a phased approach to using AI for product development and enhancement should:

- Identify impactful use cases
- Segregate use cases by those that have an operational focus (e.g., task automation, case processing, investigation analysis) and those with a more strategic focus (e.g., understanding patient experience, optimal product design).
  - For the strategic use cases, tackle products that have an abundance of available data and/or products that are not close to retirement/obsolescence. Another consideration is to segregate use cases by disease area.
- Conduct pilots and assess results
- Based on pilots and ROI achieved, expand AI and product intelligence capabilities vertically and horizontally, engage cross-functionally, and institutionalize a scalable platform that drives sustainable transformation cycles.

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