Scaling safety expertise in life sciences

A turning point in pharmacovigilance

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A holistic approach to improving drug and device safety

The mission of pharmacovigilance (PV) is to "detect, assess, understand and prevent adverse events (AEs)."[1] PV continues to grow more complex, partly due to a continuing rise in AEs, additional channels to monitor and increasingly stringent regulatory requirements. With timeliness and quality of safety operations as critical as ever, cognitive computing offers new capabilities to add speed, scale and consistency to the entire pharmacovigilance process from AE intake, triage (event prioritization), evaluation and reporting, to signal detection and assessment.

Executive summary

For over 50 years, life sciences companies have been committed to protecting patient well-being by detecting, reporting and mitigating adverse events (AEs). Yet, more than 100,000 deaths and 2 million hospital admissions each year are associated with drug or device AEs.[2] Companies must act quickly to evaluate, assess and report AEs, and identify new and serious safety signals.

Today, the pharmacovigilance (PV) process is heavily dependent on people throughout each step. With ever increasing volumes of AEs, traditional manual approaches of growing in-house teams and outsourcing are becoming unsustainable.

Manual PV approaches that rely on the effort of large teams come with endless training, introduce evaluation variability, and are subject to the limitations of human speed and effort. Industry leaders are now exploring how to apply technologies to add speed and consistency to the PV process, including: case intake, triage, medical review and reporting to regulatory bodies.

Cognitive computing offers capabilities to help handle enormous amounts of information, both structured and unstructured. It improves the ability to understand large volumes of data that humans can't handle or analyze on their own. Cognitive solutions surface insights and relationships while pointing to the supporting evidence so people can draw confident conclusions. Together, cognitive, cloud and advanced analytics can help transform patient safety from a reactive, manual process to a semi-automated, proactive source of safety insight.

Over half

of life sciences executives surveyed said they plan to adopt cognitive computing for pharmacovigilance within the next 3 years.[3]

Real-time

safety insight from proactive surveillance could be a game-changing leap forward from today's reactive approaches.

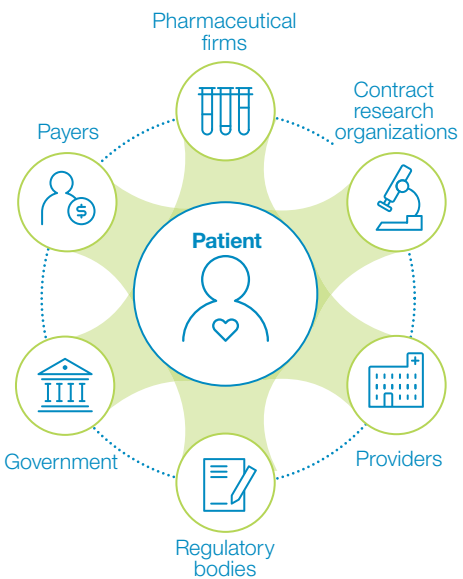
The promise

of more safety data is the insight it could yield; the potential downside is that improper analysis could yield incorrect insights and jeopardize patient well-being.

To scale PV for the future, life sciences companies will need to take advantage of the unique capabilities of cognitive computing. With such capabilities, they can improve how people discover relevant safety information; make decisions with it; and engage the safety ecosystem in new, meaningful ways that support drug and device safety (see Figure 1).

Figure 1

Parties in the PV ecosystem



Source: IBM Institute for Business Value analysis.

Traditional pharmacovigilance nears a turning point

The rise in AEs continues at a rate of about 10 percent per year.[4] Regardless of volumes, companies must report these events rapidly to regulators and act quickly on safety signals. The burden from growing event volumes is reflected in budgets that are expected to grow from an estimated USD 4 billion in 2017 to over 6 billion by 2020.[5]

Many safety signals are discovered during analysis of incoming spontaneous reports or passive surveillance – well after clinical research is complete. Real-time safety insight from proactive surveillance could be a game-changing leap forward from today's reactive approaches. Surveillance of real-world data could allow companies to detect and act upon signals earlier with an enriched understanding of the patients at risk for AEs.

But today, companies struggle just dealing with the volumes of events being reported to them via spontaneous reports and do so mostly via outsourcing and "patchwork" automation. For example, some companies employ an "auto-coder" to support Medical Dictionary for Regulatory Activities (MedDRA) coding, but this is a single isolated function in a process that entails dozens of evaluations and determinations made about the details of an AE report. To holistically improve speed, consistency, quality and insight, cognitive technologies need to be applied throughout the PV process along with other automation support via a health platform that can take in and convert data in a secure, private, stable environment.

Beyond the company's own data, other data sources offer the promise of safety insight. Electronic medical records (EMRs) and social media channels are more recent examples of channels that could be surveilled but they tend to be "noisy" – meaning data is often missing elements, contains confounding or contradictory information, and comes in a variety of formats – and data is often kept in separate repositories.

Social media is a growing channel for patients to communicate their experiences with therapeutics. In a survey, 30 percent of adults said they are likely to share information about their health on social media sites with other patients, 47 percent with doctors, 43 percent with hospitals and 32 percent with a drug company.[6] To effectively use this channel, one has to detect AEs out of colloquial, non-standard language that will often include sentence fragments or abbreviations, such as "it felt like an elephant was sitting on my chest," to describe angina.[7]

The promise of more data is the insight it could offer. The downside is that improper analysis could yield incorrect insights and jeopardize patient well-being. Pharmaceutical companies must find new ways to access and analyze data while adapting to the evolving international regulatory landscape that presents a variety of stringent reporting requirements.

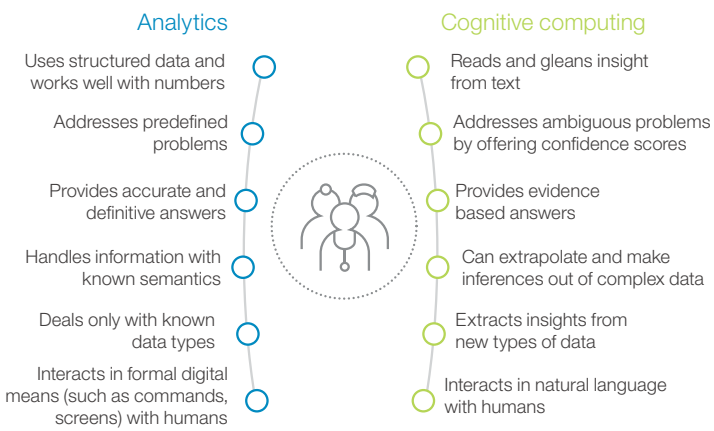
The promise of cognitive computing for PV

Advances in cognitive computing can help meet the challenges of data volume, velocity, variety and veracity. Cognitive systems can understand natural language, learn from data, make evidence-based inferences and provide confidence-weighted responses (see sidebar, "What is cognitive computing?"). These machine learning systems can quickly help locate the proverbial needle in a haystack, identifying a potential safety signal or other important safety insight.[8]

The data-driven approach of analytics and the knowledge-driven approach of cognitive computing solve different elements of business problem. So, a combination of both can reveal greater insights that either one alone could not yield. Consider the example of quantitative event rates, coupled with unstructured insights from literature and social media (see Figure 2).

Figure 2

How cognitive solutions can complement what humans do in drug safety



Source: IBM analysis.

What is cognitive computing?

Cognitive computing solutions offer various capabilities, including...

- Learning and building knowledge from various structured and unstructured sources of information
- Understanding natural language and interacting more naturally with humans
- Capturing the expertise of top performers and accelerating the development of expertise in others
- Enhancing the cognitive processes of professionals to help improve decision making
- Elevating the quality and consistency of decision making across an organization.

The cognitive computing paradigm has three capability areas that align with and specifically address the industry's need to improve PV: Discovery, Decision and Engagement.

Discovery capabilities help people recognize patterns, and discover and make connections. They can enable companies to digest vast amounts of AE data and uncover insights about adverse reactions. The discovery of safety insights is critical in signal detection and understanding drug event relationships.

Decision capabilities offer evidence-based recommendations. They can detect events out of varieties of data types, and classify and code events with confidence scores. Assessing reportability, seriousness and causality are also areas where cognitive computing can provide evidence-based recommendations and provide traceability for auditors.

Engagement capabilities enable compliance with a variety of agency requirements by recognizing both the source data, the reportability rules and the country agency where the event must be reported. These rules are constantly changing. Engage capabilities offer better collaboration among pharmaceutical companies and regulators.

Cognitive technologies can speed the extraction and evaluation of AEs. In effect, they can help scale the expertise of safety teams. Instead of reading volumes of pages and entering safety data, people can review what technologies have extracted and spend more time considering the significance of such insights, and act on them sooner. When a single solution reviews, classifies and codes each event with a single interpretation of training, variability in event evaluation is expected to be reduced, and the visibility of an emerging signal should increase.

Transforming drug safety with cognitive computing

Today, drug safety is a largely manual effort where technology is used to store data, route and submit events. Most of the effort comes from teams of hundreds of people who manually read, enter and evaluate safety data. Reliance on people creates scalability and consistency challenges throughout the process.

Adding safety personnel to deal with volume introduces several challenges. Human teams are limited in speed and productivity; costs go up linearly as teams grow; and the potential for delays during volume surges is constantly monitored. Team growth introduces the challenge of variability – such as individuals interpreting data differently and evaluating events inconsistently. This potential variability requires more frequent quality control checks that add to case processing time.

Cognitive solutions can not only help contend with data scale, but also offer consistency in case evaluation (see "Pilots in individual safety case reports (ICSRs) and MedDRA coding"). Events should be reported faster, and safety issues detected earlier and with greater confidence, as the consistency in evaluation helps to raise issues more visibly.

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Pilots in individual safety case reports (ICSRs) and MedDRA coding

To evaluate whether cognitive computing could benefit drug safety teams' efforts, pilots in ICSR detection and MedDRA coding have been conducted with a few large pharmaceutical firms. The objective of these pilots was to assess the accuracy of cognitive technologies in reading complex text to detect the four elements of a reportable event and propose a MedDRA code while pointing to the supporting sentences. In each case, these solutions are trained with several thousand events labeled and classified by subject matter experts (SMEs) who have validated the ICSR elements and MedDRA codes within their own organizations.

After providing this data to a cognitive model that has been designed to look for specific text features like drug names, events and connecting verbs, that model is tested on sample AE data. The cognitive results are reviewed by SMEs for accuracy and model adjustments are made. In each of these small pilots, cognitive solutions were able to reach approximately 80 percent accuracy in both ICSR detection and MedDRA coding in a short time frame. These results signaled that these capabilities show promise and potential benefit.

Stringing together many cognitive modules could accelerate the review of AEs. Detecting ICSRs could help a company parse out the reportable events, thereby narrowing the number that have to be reviewed further and reported to agencies. Adding many of these cognitive services like assessing seriousness, and expectedness offers the hope that safety teams can spend time evaluating the data extracted by a cognitive system, and focusing on serious and complex cases versus reading innumerable pages to find the relevant sentences.

Beyond case processing, cognitive solutions could enable proactive surveillance using external real-world data sources. Administrative claims data, EMR data and social media are abundant sources of information about patients' experiences with therapeutics. If a company could combine the events reported to them with these other sources, they might be able to detect, validate and act on signals earlier to protect patient well-being. These sources might also offer additional insights such as patient characteristics, risk factors or event features that may define the signal more specifically.

To extract meaningful PV insights from these new and varied types of data, life sciences companies need technologies that can ingest, traverse, interpret, normalize and analyze that data to offer a single integrated view of an intervention's risk and benefit profile over time. The industry needs new, flexible, configurable capabilities to extract each agency's required information and submit reports in the specific format required by each regulatory body.

Together, cognitive, cloud and advanced analytics can help transform safety from a reactive, manual process to a semi-automated, proactive source of safety insight. By converting safety data into information with greater speed, consistency and enrichment, companies may be able to act earlier and with greater confidence to address safety issues (see Figure 3).

Figure 3 illustrates how a cognitive solution might speed AE case processing. A cognitive solution extracts key case elements – and from millions of pages – so that the team is focused on review and evaluation instead of reading and extracting "by hand."

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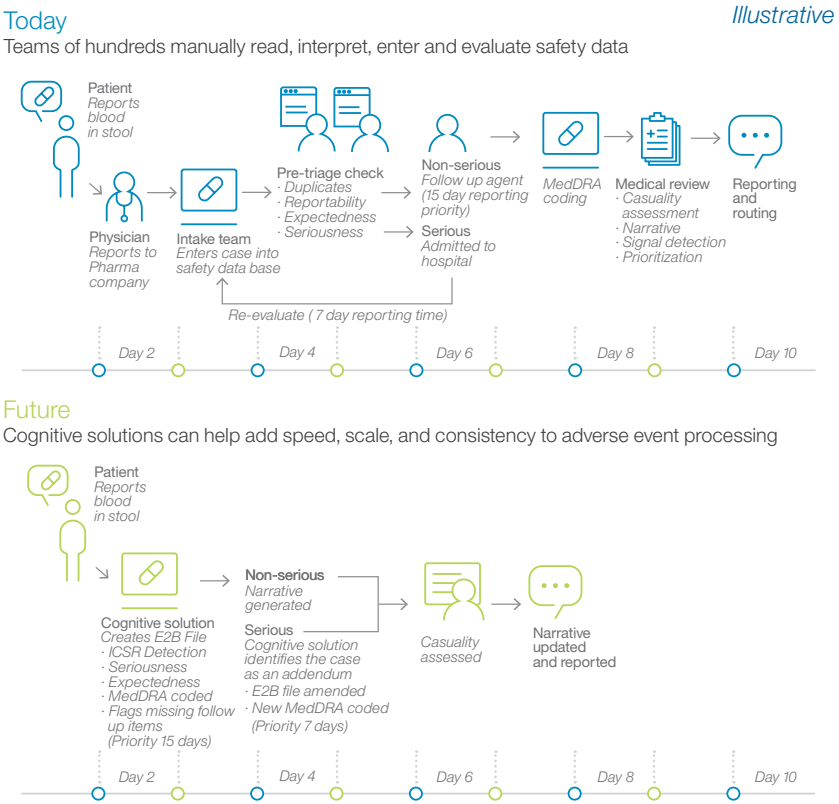
Figure 3

Comparing today's typical PV workflow to a possible end-to-end process enhanced with using cognitive capabilities

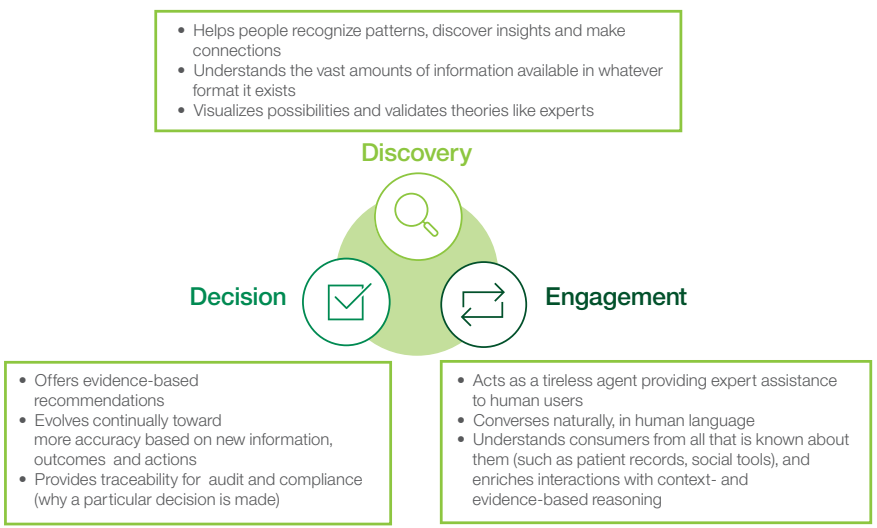


Source: Chart created by IBM as a representation based on interviews with the IBM Watson Health Pharmacovigilance Innovation Council.

As the illustrative example shows, cognitive solutions may help add speed, scale, and consistency to AE processing. Unlike humans, cognitive solutions are infinitely scalable. With a single solution classifying coding and assessing events, speed and consistency in data evaluation should improve (see Figure 4).

Figure 4

Cognitive computing may bring new value to pharmacovigilance

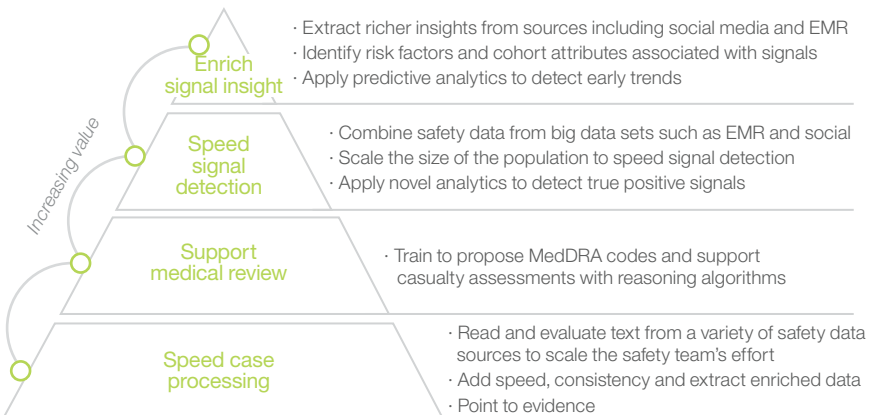


Source: IBM Institute for Business Value analysis.

Cognitive technologies can supplement the capabilities of human beings, helping people make novel discoveries out of safety data, make evidence-based decisions about the implications of safety data, and engaging regulatory agencies in the manner and in the time frames they require (see Figure 5).

Figure 5

As cognitive solutions are implemented, early benefits may include speed. But later, the benefits of consistent data review, classification and coding may be seen in signal analysis



Source: IBM Institute for Business Value analysis.

Recommendations

Understand your business metrics and assess the impact of cognitive

- Evaluate the labor and technology costs of case processing now, and the future.
- Define success metrics that underlie the business case. Chart a course for applying cognitive capabilities.
- Develop your organization's cognitive computing plans. Be realistic about value realization that may require initial investment before seeing returns.

Create momentum within the organization for transformation

- Educate your stakeholders about cognitive capabilities and get agreement that current efforts are unsustainable. Forecast event growth and human cost increases.
- Create the business case for cognitive. Understand that initial implementations come with certain upfront costs so that expectations about timing of ROI are realistic. Upon gaining stakeholder buy-in, test and validate use case scenarios with users.
- Develop and train the system. Plan to extract the right quantity and quality of data.

Plan for and implement change in a controlled manner where users can supervise the cognitive solution

- Involve executives throughout the cognitive journey. Deploy the baseline solution.
- Communicate the cognitive vision at all levels. Supervise learning and performance. Measure success, correct, adjust and re-test.
- Continue to raise the "cognitive IQ level" of the organization by regularly communicating the ongoing progress. Define the next phase of implementation.

Related publications

Fraser, Heather, Lauren E. O'Donnell, Louisa Roberts and Sandipan Sarkar. "Prescribing a digital transformation for life sciences: Your cognitive future in life sciences." IBM Institute for Business Value. March 2016. ibm.biz/cognitivels

Fraser, Heather; Sandipan Sarkar; and Dave Zaharchuk. "A booster shot for health and wellness: Your cognitive future in the healthcare industry." IBM Institute for Business Value. September 2015. ibm.biz/cognitivehealth

Fraser, Heather, Anthony Marshall and Teri Melese. "Reinventing life sciences: How emerging ecosystems fuel innovation." IBM Institute for Business Value. April 2015. ibm.biz/reinventingls

Are you ready to improve AE management through cognitive capabilities?

- At what rate are your AEs anticipated to rise and what is your plan for managing the increase?
- What is the current cost of relying on humans to do the work of case intake and processing? How much do you expect those overall costs to increase?
- What technologies do you use for case processing? Do they support consistency, speed and compliance?
- How will you integrate data from multiple channels throughout the phases of drug development? In what ways can you derive integrated safety insights from external data sources?
- What tools and data sources do you use for signal detection, validation and insight? How much time and cost are required to detect, validate and investigate a signal to the required level?

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Venkat Venkataramanan, Associate Partner, Watson Health Consulting

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Notes and sources

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