

opentext™

Contents

Life Sciences is changing. How can organizations respond?	3
Towards the Al-powered analytics platform	10
Al-enhanced analytics with OpenText Magellan	11

75% of Life Sciences companies believe that AI will improve process, operations and outcomes for their company.

OpenText research

Life Sciences is changing. How can organizations respond?

Current business models for Life Sciences companies are no longer sustainable. The cost of drug development has exploded over the last 20 years while patient outcomes have worsened. Governments around the world are focused on driving down what they perceive as an unacceptably high cost of medicines. The sector is increasingly moving to a value-based pricing model, where payment is determined by demonstrable results. Achieving innovation and outcomes at a lower cost is imperative. This white paper examines how Life Sciences organizations can use Al-powered analytics to make data-driven decisions to meet these challenges.

The Life Sciences sector has always generated a vast amount of data from scientific research, clinical trials, patient profiling, compliance and regulatory requirements. The volume and variety of data continues to grow. Estimates suggest that the amount of medical data doubles every three years. As the data provided through new biomedical research, clinical evidence, epidemiological studies, commercial transactions and social media increase in speed and size, so do the challenges of managing and analyzing that data for maximum business advantage.

These challenges have never been more pressing, as the operating environment for Life Sciences companies gets more complex. The costs of research and development have grown while the window to break even has shrunk. The increasing use of generic drugs is undermining the profit of branded medicines and personalized and patient-centric approaches require new business models. In addition, tighter regulatory controls and increased worldwide regulatory requirements and costs place an extra strain on Life Sciences companies.

By combining all types of data, such as real-world outcomes data, clinical data, genetic data, demographic data and patient sentiment data, organizations can gain actionable insight. This translates into more efficient clinical trials, accelerated discovery and approval of new medicines, improved production and supply chain operations and more targeted sales and marketing.



100% of Life
Sciences
companies
surveyed said
they will begin
evaluating
Al within the next
12 months—
although more than
one-fifth admitted
they didn't know
where to start with
implementing
the technology.

OpenText research

The Life Sciences sector has invested in business intelligence and analysis tools. But when managing big data, traditional analytics solutions are unable to provide the insights quickly enough for business. It is not just the massive volume of data but also the diversity of data types. The wealth of medical, research and patient data in a wide variety of unstructured formats is often inaccessible or spread across tens, if not hundreds, of sources inside and outside of the organization.

Traditional data management and data analytics approaches need to be augmented with a technology that quickly and effectively delivers insight from that data. Artificial Intelligence (AI) combines capabilities such as machine learning and natural language processing (NLP) with advanced analytics to revolutionize almost every aspect of Life Sciences.

Life Sciences professionals are beginning to understand the potential for Al. A recent survey of Life Sciences companies worldwide, conducted by OpenText, found that three quarters of respondents thought that Al will benefit process, operations and outcomes in their business⁵.

The need for Al-powered analytics

Every Life Sciences company surveyed by OpenText said they will be evaluating Al within the next 12 months. However, more than one-fifth of companies admitted they did not know where to begin with implementing the technology. For most organizations, this will start with the increased automation of key business and production processes. However, the major benefit for Life Sciences companies will come through the effective combination of Al and analytics—called Al-powered analytics.

Al-powered analytics address many of the weaknesses of previous data analytics solutions to meet today's big data environment. The majority of analytics solutions used in the industry are focused on transactions. They provide intelligence into the functioning of day-to-day business process and help retrieve data and build reports aimed at improving performance in production, maintenance, quality management and accounting.



These systems were never designed to handle the volume and variety of data required today. They are based on historical data and lag behind in providing crucial insights prior to a business event happening.

In addition, while data is readily available in vast content repositories, it is of varying quality or relevance. However, the real challenge is the volume and variety of data. The data are stored in many locations with many layers. It is no longer enough to Recording and reporting on the data is no longer sufficient. Life Sciences analytics must be capable of understanding, interacting, predicting and responding to the data. Enhancing analytics capabilities through the automation of repetitive cognitive tasks enables Life Sciences companies to reduce risk by identifying potential issues and initiating a workflow to correct the problem.

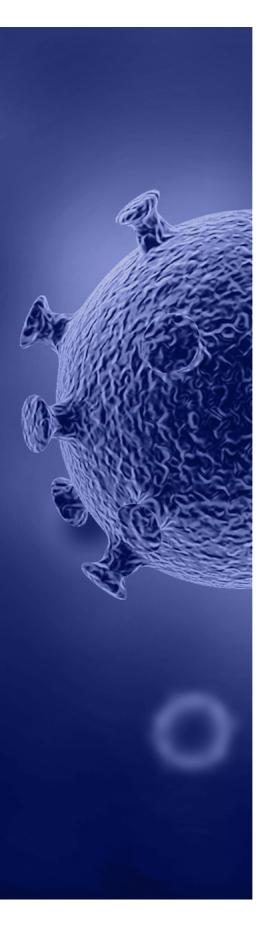
The key benefit of AI is the capability to trawl vast data sets quickly and to continually learn from what it finds. It can differentiate between complex data sets more effectively than a human and see patterns and trends in incomplete or seemingly unrelated data sets. The insight leads to faster and better discoveries. It could be the difference between finding a vital biomarker or not.

Research suggests the Life Sciences industry is beginning to benefit from Al-powered analytics. Market research company, Frost and Sullivan has found that using Al as part of a decision support tool has led to excellent treatment and patient outcomes.

Accenture's analysis estimates that Al can potentially save the US healthcare industry \$150 billion by 2026.⁶

Data for an individual patient can include:

- Electronic Medical Records (EMRs).
- Machine generated/sensor data from wearables and other Internet of Medical Things (IoMT) devices (monitoring blood pressure, diabetes, heart rate, etc.).
- Clinical data from CPOE (computerized physician order entry) and clinical decision support systems (physician's written notes and prescriptions, medical imaging, laboratory, pharmacy, insurance and other administrative data).
- · Social posts and online activities.
- Relevant clinical trial and post-market surveillance data.
- Less patient-specific information (including emergency care data, public health statistics, news feeds and scientific research articles).



The key drivers

Al-powered analytics can improve the Life Sciences industry in many areas, including more effective clinical trials, enhanced product innovation and development and increased patient-centric delivery. Adoption will be influenced by the following business drivers:

Improving patient outcomes

The science of medicine is fundamentally changing from predominately treating illness to improving diagnostics and personalized treatments. This is leading to massive increases in chemical, biological and data analysis. At the same time, personalized, patient-centric treatment plans are possible with a holistic view of each individual provided by a variety of sources, including EMRs and self-generated patient data from wearable devices.

Lowering the cost of medical products

Governments worldwide are responding to high drug prices with international legislation such as the Affordable Care Act in the US. With costs of drug development rising and generics continually eroding margins, pharmaceutical companies need to find ways to speed the drug development and approval process and reduce the costs of development and delivery. Analyzing data from every aspect of development can help find areas where greater automation and efficiency is possible.

Moving to value-based pricing

While criticism around the value-based pricing model remains, there is no doubt this is the direction the Life Sciences sector is taking. This makes it even more important for organizations to deploy data to defend research budgets and profit margins. Organizations will increasingly need to integrate real-world evidence with clinical trial data and genomic research to demonstrate the value of their treatments based on patient outcomes.

Improving quality

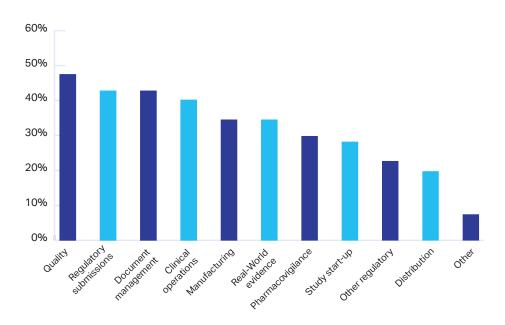
All companies have an emphasis on delivering patient safety through the highest quality product possible. This requires both an internal and external focus. Internally, data analysis must be applied to ensure the most efficient production operations and lowest product failure rate. Externally, product efficacy now requires the integration of real-world data as well as post-market surveillance data to inform the development of existing products and creation of new solutions.

Compliance, risk and fraud

Compliance and fraud risks are on the rise for Life Sciences organizations. Risks include off-label marketing, product divergence and the misuse of personal data. To keep up with today's compliance demands at a global regulatory and industry standard level, companies must take a proactive, integrated approach to data analysis across a range of business, production and supply chain systems.

With the focus on becoming data-driven, Al-powered analytics offers Life Sciences companies many benefits. OpenText research shows that Life Sciences professionals are clear where Al-powered analytics can help their business (see figure 1)—primarily in operations and compliance. The survey showed that almost seven percent of organizations have already used Al to extend their analytics capabilities.

opentext



The key business areas where Al-powered analytics offers the greatest benefit Source: OpenText research

The key use cases

While almost every part of an organization can benefit from Al-powered analytics, it is particularly suited to the following areas:

Patient care and outcomes

With Al-powered analytics, Life Sciences firms can become truly patient-centric. It allows pharmaceutical companies, medical device manufacturers, HCPs and insurers to more closely align their goals with those of their patient to develop preventative and outcomerelated approaches. By accessing and analyzing data from disparate sources, such as EMRs, clinical trial data and social channels, companies can deliver deeper medical insights to healthcare professionals and direct to the patient.

As more people manage their health using wearable IoT devices, such as the Fitbit® and mobile apps, the volume of data that helps companies understand the patient journey grows. This can lead to real-time and personalized healthcare, where the individual's health can be managed based on the latest data—providing advice where proactive care and lifestyle changes will remove the need for direct intervention.

Clinical trials

Clinical trial planning and design can benefit from Al-power analytics, especially within trial recruitment and enrollment. Using data from previous trials and comparable trials as well as patient and EMR data, allows for more accurate patient profiling and identification. It will help clinical study teams better estimate the time needed to recruit the required number of trial subjects. They can refine resource and planning estimates while automating the process so they are notified before delays or problems arise.



Research and development

For Life Sciences organizations, clinical trials are often the largest part of any R&D budget. However, as regulatory requirements continue to tighten and research and development costs continue to rise, there is a need to continually improve productivity. Using Al-powered analytics, organizations can better analyze the results of clinical trials and patient records to identify follow-on indications and discover adverse effects before products reach the market. In addition, Al-powered analytics deliver insights from data that were simply not available before. Although still in its infancy, this element of Al can infer relationships between biological entities that were previously hidden to accelerate innovation and discovery while shortening the product development process.

Production and manufacturing

As with any other manufacturing operation, Life Sciences manufacturers need to ensure optimum capacity for their production facilities. However, when patient safety is concerned, quality management becomes a major issue. Deploying Al-powered analytics allows for the close management of the production process as well as managing through risk to minimize the chance of impurities in a formulated drug product.

Applying Al to root-cause analysis—a key aspect of a corrective and preventive action (CAPA) strategy—allows organizations to efficiently identify the main causes for reported product defects and to analyze product failures to understand the impact of identified causes and manage the overall defect count. When allied to data from previous production runs, capacity and operational data, this improves resource planning and management.

Accounting and finance

Accounting and finance departments can apply Al-enhanced analytics to improve their cash-based processes. It can learn the criteria for handling invoices to automate invoice processing and provide insight to the accounts receivable department that can be used in securing financing options. In addition, it can accelerate payments by automatically validating and processing invoices, allowing the accounts payable department to secure early payment discounts. When errors occur, the system can react automatically or suggest resolution options to accounts payable staff.

Sales and marketing

Pharmaceutical firms can leverage Al-powered analytics to improve sales forecasting by analyzing previous sales activity, customer purchasing patterns, market sentiment, competitor pricing and demographic sales trends to provide highly accurate pictures of future sales opportunities. In sales negotiations, sales representatives can apply machine learning that draws on insight from contracts and related documents, customer and competitor behaviors and market analysis that can help land the sale. In addition, digital marketing can apply Al-powered analytics to more fully understand customer perceptions about their products, which channels are most likely to convert and which marketing campaigns deliver the most return.

opentext

Supply chain optimization

Life Sciences companies are increasingly involved in extended partner ecosystems, working closely with CROs, suppliers, customers, academic bodies and regulators. Managing the supply chain becomes more important as companies rely more heavily on—and spend more with—a wide range of suppliers. Al-powered analytics can help improve supply chain automation and visibility. It allows for real-time management of supplier relationships and performance, as well as improved contingency planning and business continuity. It can use a combination of internal and external data to help reduce unforeseen shortages and supply chain disruptions affecting customer service levels and sales revenues.

Regulatory and industry compliance

Healthcare reform, changing regulatory requirements and globalization have all added to the compliance and risk burden for every Life Sciences organization. The requirements and penalties are now so far-reaching that compliance and legal departments must reach out across the entire organization and work with data from all business functions. Alpowered analytics eases the discovery and retrieval process by mining all data, structured and unstructured, to drive risk planning through the early detection of anomalies and exceptions that may fall outside of compliance requirements. Within pharmacovigilance, for example, real-world patient data can be integrated with EMR data to minimize risk and improve drug safety.

Applying Al-powered analytics to key business activities

Business activity	Analytics
Research and development	Target/biomarker identification
	Portfolio optimization
	Competitive benchmarking
Clinical operations	Trial planning and efficiency
	Scenario planning
	Trial design
	 Cohort identification and segmentation
	Trial recruitment
Product development	Safety monitoring
	 Forecasting
	Resource allocation
	Product failure analysis
	Product risk analysis
Manufacturing and supply chain	Supplier performance and compliance
	Product and batch quality
	Inventory management
	Demand planning and forecasting
	Manufacturing asset productivity and effectiveness
Patient outcome	Preventative/self-managed care
	Early diagnosis and triage
	Doctor and HCP decision support
	Post-market surveillance
	Online/social sentiment analysis



Towards the Al-powered analytics platform

For Life Sciences companies to fully exploit the value in their data requires an enterprise-wide, Al-powered analytics platform. A new generation of platforms combines open source machine learning with advanced analytics and enterprise-grade business intelligence to enable machine-assisted decision-making, automation and business optimization. These should:

Integrate AI and analytics

Al-powered analytics do not require a 'rip-and-replace' strategy. It is an enhancement of current analytics capabilities that layers cognitive intelligence and machine learning on top of transactional and predictive analytics solutions.

Data and content

While it can be simple to identify and access data, the unstructured nature of many content types makes it difficult to access the data they hold. Using traditional techniques, organizations struggle to mine the structured and unstructured data in content. Consequently, a great deal of knowledge and insight remains untapped in document-centric processes. This challenge is becoming more prevalent as business content is increasingly non-textual, for example video and images. Al-powered analytics combines machine and deep learning with advanced categorization and meta-tagging to make the data within all content available for analysis in ways not previously possible.

Data access and quality

With Al-powered analytics, organizations can gain insight from data created both internally and within trading partner communities. For example, the research and development functions create huge volumes of data, which is supplemented by a growing number of data sets from other trials, EMRs and real-world data from patient devices. The data must be accessed, cleansed and normalized. Research shows that access to data and ensuring data quality are two of the biggest barriers to Al programs. An Al-powered analytics platform must include advanced data management and data quality features to help ensure a firm basis to deliver accurate outputs and insight.

Data democratization

Until recently, most analytics tools were reserved for data scientists and power users. However, the full benefit of data analysis is only realized when everyone who needs it has the insight available to them in a format they can use. This requires the 'democratization' of data where different users gain access to the data at a level that is right for them. In this scenario, data scientists create the algorithms that are passed to the business operational users.

In addition, users should be able to design their own outputs and reports that give them access to the information they need in a format they understand. Using machine learning and natural language processing, it is becoming possible to use Al-powered analytics for users to delve into massive amounts of data using simple 'plain language' questions.

While more than 20% of Life Sciences companies say they are already benefiting from AI, fewer than 7% have used AI to extend their analytics capabilities.

OpenText research

Open source

Some Al and analytics solutions have been based around 'black box' proprietary algorithms. This is a sound approach, but it doesn't promote agility and innovation. The alternative is a new generation of open source Al-powered analytics, such as OpenText™ Magellan™, which offer a comprehensive set of APIs to create communities of Life Sciences professionals, data scientists and developers. Communities are already coming together, such as healthcare.ai, to pioneer open source Al development in healthcare. The open source route encourages innovation, with an active community that provides a virtuous loop to drives quality and reliability for faster drug development and business efficiencies.

Transparency of outcome

For all its promise, many people still view AI as potentially harmful to society.9 Especially where AI-powered analytics provide decision support for doctors and nurses, patient safety should dictate that the person should be able to understand how and why that decision was reached. In fact, it is very likely that this will quickly become mandated, as the GDPR legislation in Europe gives individuals the 'right of explanation over any decision reached with AI support.¹⁰ The black box approach to AI and analytics makes this level of transparency difficult but the transparent nature of open source AI algorithms facilitates the process of explaining AI-driven decisions to patients.

Al-powered analytics are set to revolutionize the way Life Sciences organizations use the massive volumes of data they have to drive insight and informed decisions. Applying advanced analytics techniques and machine learning to big data allows companies to access all their data and content to identify relationships, trends and patterns in ways that have not been possible before. Combined, Al and analytics have the potential to unlock hidden connections that humans are likely to miss that can aid in everything from drug discovery to personalized healthcare.

Al-enhanced analytics with OpenText Magellan

Magellan is a flexible, Al-enhanced analytics platform that combines open source machine learning with advanced analytics, enterprise-grade business intelligence and natural language recognition capabilities to acquire, merge, manage and analyze big data and big content stored in Enterprise Information Management systems. Magellan enables machine-assisted decision making, automation and business optimization at speed and scale.

Based on open APIs and algorithms, Magellan allows communities of data scientists, Life Sciences professionals and developers to work together to accelerate innovation and continually improve the quality and outputs of AI-powered analytics solutions.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: opentext.com.

Connect with us:

- OpenText CEO Mark Barrenechea's blog
- Twitter | LinkedIn

opentext

References

- Brayne, Sophie; McKellar, Scott; Tzasfestas, Kyriakos. Artificial Intelligence in the Life Sciences & Patent Analytics: Market Developments and Intellectual Property Landscape (2018) https://www.ip-pragmatics.com/media/1049/ip-pragmatics-artificial-intelligence-white-paper.pdf
- 2. EY. Beyond borders: staying the course (2017) http://www.ey.com/Publication/ vwLUAssets/ey-biotechnology-report-2017-beyond-borders-staying-thecourse/\$FILE/ey-biotechnology-report-2017-beyond-borders-staying-the-course.pdf
- Kulkarni, Rohan. Managed Healthcare Executive, Top 5 ways value based pricing impacts healthcare (2016) http://managedhealthcareexecutive.modernmedicine.com/ managed-healthcare-executive/news/top-5-ways-value-based-pricing-impacts-healthcare
- Densen, Peter. Managed Healthcare Executive, Challenges and opportunities facing medical education (2011) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116346/pdf/ tacca122000048.pdf
- 5. OpenText. Artificial Intelligence in the Life Sciences survey (2017)
- Frost and Sullivan. Transforming Healthcare Through Artificial Intelligence Systems (2016) http://ai-healthandlifesciences.com/hypfiles/uploads/2016/08/Al-Healthcare-Research-Insights-KisacoResearch.pdf
- 7. Accenture. Accenture Predictive Health Intelligence (2014) https://www.accenture.com/t00010101T000000Z_w_/gb-en/_acnmedia/Accenture/Conversion-Assets/DotCom/Documents/Global/PDF/Industries_1/Accenture-Predictive-Health-Intelligence.pdf
- 8. InsideHPC. Survey shows how AI can revolutionize life sciences (2018) https://insidehpc.com/2018/01/survey-shows-ai-revolutionize-life-sciences/
- Sulleyman, Aatif. The Independent, AI is highly likely to destroy humans, Elon Musk warns (2017) http://www.independent.co.uk/life-style/gadgets-and-tech/news/elonmusk-artificial-intelligence-openai-neuralink-ai-warning-a8074821.html
- Burt, Andrew. Is there a 'right to explanation' for machine learning in the GDPR? (2017) https://iapp.org/news/a/is-there-a-right-to-explanation-for-machine-learning-in-the-gdpr/