sorcero

Language Intelligence for Medical and Regulatory Affairs

How new AI technology is transforming life sciences

Medical Affairs is rapidly establishing itself as the third pillar of life sciences, but its value can often be intangible and thus underappreciated. The numbers and types of users of data communicated by Medical Affairs have grown and the demand for data transparency has accelerated, new opportunities for Medical Affairs to emerge as a bolder organization to proactively drive strategy, generate evidence, and influence patient outcomes.

A Sorcero White Paper

Content

Executive Summary

Medical Affairs is establishing itself as the "third pillar" of life sciences alongside R&D and Commercial, but its value can be intangible and thus underappreciated. As the audience for data communicated by Medical Affairs has grown in both number and type, the demand for data transparency has accelerated. There are new opportunities for Medical Affairs to emerge as a bolder and more agile organization that proactively generates evidence, drives strategy, and influences patient outcomes.

A new generation of Medical Affairs leaders is analyzing more data than ever to improve clinical decision-making, replacing the outdated, reactive model of MA as a supportive function in the biopharmaceutical industry. This transformation requires increasingly sophisticated digital support tools to maximize the impact of Medical Affairs and increase its value proposition.

While artificial intelligence (AI) is a hot topic in healthcare and life sciences, the role of AI in Medical Affairs is often overlooked. The most sophisticated AI and machine learning (ML) solutions on the market require training on vast data sets that exhaust the supply of even large medical fields such as oncology. As a consequence, these models are generalists unable to work well with technical language. Conversely, custom-built AI solutions seek out the traditional revenue-generating arms of life sciences, R&D and Commercial. Consequently, MA teams have lagged in adopting AI to keep up with the rapidly growing flow of medical and scientific information.

The absence of a sophisticated AI solution for Medical Affairs represents a missed opportunity to capitalize on the wealth of data flowing through Medical Affairs. It's particularly striking because this data is the critical function of MA and is often framed as a problem--keeping up with the exponentially increasing amount of information generated by publications, conferences, congresses, social media, key opinion leaders (KOLs), and insights generated in the field. Medical Affairs is too often viewed by life sciences as a cost center. MA teams are being asked to do more with less while missing out on the advanced tools available to other segments of the life sciences.

This is where Language Intelligence steps in to fill the gap. Language Intelligence is a cutting-edge technology that enables advanced language models to work with custom ontologies to deliver powerful AI applications to a specific sector, organization, or workflow. This solution allows the most advanced AI language models to quickly become experts in workflows in Medical Affairs and Regulatory Affairs, generating value from the sector's data and reinforcing its value both to its organization and to the key clinical decisions that determine patient outcomes.

> A bolder and more agile generation of Medical Affairs is emerging as a strategic leader in generating evidence and influencing patient outcomes, replacing the outdated model of MA a supportive function in the biopharmaceutical industry.

AI trends in life sciences

Life sciences companies have been investing in AI for years but investment has both accelerated and broadened after the COVID-19 pandemic demonstrated that companies could be managed remotely and with digital solutions. In its 2020 report, "Scaling up AI across the life sciences value chain" Deloitte reported that "more than 60% of life sciences companies spent over US$20 million on AI initiatives in 2019, and more than half expect investments in AI to increase in 2020." These investments are reaping enormous rewards, driving billions of dollars worth of new drugs, annual savings, and increased opportunities across the sector.

Traditionally, this investment is highly concentrated in drug discovery. According to the Artificial Intelligence Index, an annual report produced by Stanford's Institute for Human Centered-AI, the money committed to AI-powered drug discovery soared to $13.8 billion in 2020, 4.5 times the number invested just the year prior. Similarly, a recent article in PharmaVoice ("Artificial Intelligence and Machine Learning", 2018) discussed a wide variety of AI and ML use cases for life sciences with a heavy emphasis on clinical and R&D applications without referencing Medical or Regulatory Affairs.

This bears out in the market. According to a recent report from McKinsey, only 10 percent of life sciences companies say that they are 'investors' in Medical Affairs solutions that enable real-time exchange between corporate headquarters and field medical or that facilitate immediate access to information for MSLs and KOLs, moving relationships into virtual formats. Though adoption has increased since the report was released in 2018, many of the tools used are relatively primitive compared to the more modern investment in technology for R&D and Commercial.

This leads to a vicious cycle--Medical Affairs deals with a wealth of information that drives value for life sciences companies, but without the proper investment in technology to analyze the information and put it into action, the potential of Medical Affairs goes unrealized--leading to continued under-investment. This lack of investment in cutting-edge technology prevents MA from realizing its full potential and making the case for its proper value to its enterprise.

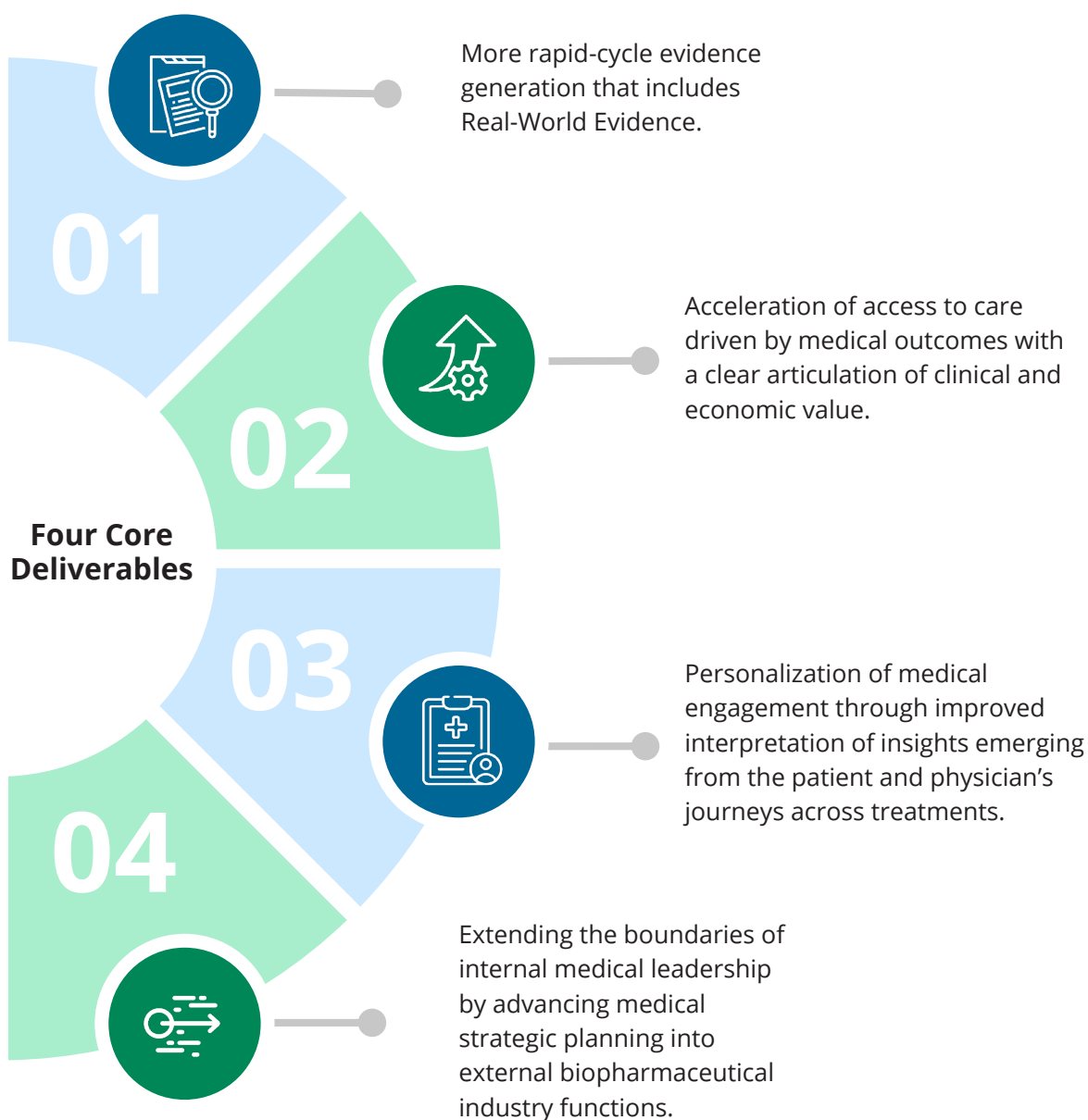| **Deloitte.**	In its 2020 report, "Scaling up AI across the life sciences value chain" Deloitte reported that "more than 60% of life sciences companies spent over US$20 million on AI initiatives in 2019, and more than half expect investments in AI to increase in 2020."
PharmaVOICE.com	A recent article in PharmaVoice ("Artificial Intelligence and Machine Learning", 2018) discussed a wide variety of AI and ML use cases for life sciences with a heavy emphasis on clinical and R&D applications without ever mentioning Medical Affairs directly.
McKinsey & Company	According to a recent report from McKinsey, only 10 percent of life sciences companies say that they are 'investors' in Medical Affairs solutions that enable real-time exchange between corporate headquarters and field medical or that facilitate immediate access to information for MSLs and KOLs, moving relationships into virtual formats."

Medical Affairs is on the rise- so is its complexity

For several years, shifting healthcare provider (HCP) interaction paradigms have elevated the role of Medical Affairs and its impact on the bottom line. A 2019 McKinsey and Associates whitepaper, "A Vision for Medical Affairs in 2025", details how the most successful organizations will learn how to combine and analyze disparate databases of information to better inform their interactions with healthcare professionals and a growing number of stakeholders.

The report highlights four core deliverables of this bold new generation of Medical Affairs teams:

01

More rapid-cycle evidence generation that includes Real-World Evidence.

02

Acceleration of access to care driven by medical outcomes with a clear articulation of clinical and economic value.

Four Core Deliverables

03

Personalization of medical engagement through improved interpretation of insights emerging from the patient and physician's journeys across treatments.

04

Extending the boundaries of internal medical leadership by advancing medical strategic planning into external biopharmaceutical industry functions.
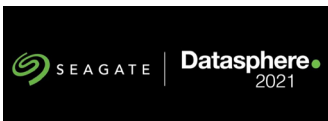
In a more transparent and technologically savvy world, Medical Affairs is responding to HCP's desire for more real-world evidence and for a more connected relationship with life sciences companies. A 2017 Bain and Company report, "Reinventing the Role of Medical Affairs", described why Medical Affairs will continue to grow in complexity and responsibility: "An experienced Medical Affairs team can link scientific and clinical results to patient outcomes. adding value at every stage of a drug's development." The report explained that. "when discussing a potential new compound with physicians, payers and opinion leaders, for example, Medical Affairs teams gather vital feedback on its market potential and patient needs at the earliest stages of the drug development process." Furthermore, the article continued, "the insights these teams glean over time can improve return on investment and create a strong competitive advantage by helping companies design more effective clinical programs and launches".

In addition, Medical Affairs faces a common problem within life sciences-a constantly rising sea of information that is increasingly difficult to cover. Information streams in from a plethora of conferences, congresses, articles, journals, and social media, growing at an exponential rate. According to a report by Seagate, the healthcare "datasphere" is expected to grow at an astonishing 36% CAGR from 2018 to 2025--almost doubling every two years. Overworked teams are unable to keep up using existing tools and manual review.

This relentless surge in information presents a crisis, but also an opportunity. With more data than ever, life sciences companies are able to refine the once-nebulous impact of Medical Affairs into something much more quantifiable. KOL influence can be tracked and measured, and new metrics such as Scientific Share of Voice (SSoV)--the number of mentions of a company's product, device, or strategy as a percentage of all mentions of that category of product, device, or strategy. SSoV is increasingly easy to capture across the vast life sciences datasphere, delivering a topline key performance indicator (KPI) for Medical Affairs.

BAIN & COMPANY

A 2017 **Bain and Company** report, "Reinventing the Role of Medical Affairs", described why Medical Affairs will continue to grow in complexity and responsibility: "An experienced Medical Affairs team can link scientific and clinical results to patient outcomes. adding value at every stage of a drug's development."

SEAGATE | Datasphere 2021

According to a report by **Seagate**, the healthcare "datasphere" is expected to grow at an astonishing 36% CAGR from 2018 to 2025--almost doubling every two years. Overworked teams are unable to keep up using existing tools and manual review.

> **"**
> The most successful organizations will learn how to combine and analyze disparate databases of information to better inform their interactions with healthcare professionals and a growing number of stakeholders.

Not all AI is equal - What is Language Intelligence?

Most kinds of AI and ML are not well suited to meet modern Medical Affairs challenges. AI advances have lately gone in two main directions, which have overlooked MA. Traditional applications of AI have focused on machine learning solutions dedicated to specific, high-value problems such as drug discovery. The pressure to develop drugs quicker and more efficiently and the enormous profits of developing a hit drug allow for significant investment in custom AI solutions. According to the Artificial Intelligence Index, the life sciences industry committed $13.8 billion to AI-assisted drug discovery in 2020, 4.5 times more than was invested in 2019.

When it comes to the language-based AI solutions that could benefit Medical Affairs, advances in the field have come from adding an increasing number of parameters to neural networks and then training them on vast amounts of information, ingesting all of Wikipedia or scraping the entire open web. The cost of these models is growing exponentially--it is estimated that Google spent over $10 million to build and train its T5 model. But with savings estimated to run into the tens of millions annually for top life sciences companies, cost is not the limiting factor.

The larger the models grow, the more data-hungry they become. The C4 dataset, for instance, contains 15 billion words. Even if life sciences companies were able to invest the necessary money into the technology behind a large language model, they could not gather enough information to adequately train the models on a specific workflow. Conversely, general language models excel at general language problems, but their accuracy collapses when dealing with technical language. These challenges have resulted in an under-investment in AI for Medical Affairs.

This is where Sorcero's Language Intelligence platform steps in to fill the gap. Language Intelligence is the breakthrough technology that allows the most advanced language models to work with ontologies. As a result, general language models can quickly become experts on the technical language that defines specific life sciences workflows. The resulting solutions combine the power of the largest language models with the accuracy of custom ontologies, delivering transformative AI solutions for Medical Affairs.

Unlike some forms of AI like robot process automation (RPA), LI is not designed to replace workers. RPA automates low-level tasks, such as filling out forms and spreadsheets. Language Intelligence, by contrast, is designed to augment expert workers on cognitively intense tasks. Through its knowledge of specific technical content, it identifies key passages and terms and directs experts to them in order to make decisions quickly. It also delivers insights, metrics, and advanced analytics that allow experts to quickly identify patterns and trends from large datasets.

$13.8 billion in 2020

According to the Artificial Intelligence Index, the life sciences industry committed $13.8 billion to AI-assisted drug discovery in 2020, 4.5 times more than was invested in 2019.

$10 million

The cost of these models is growing exponentially--it is estimated that Google spent over $10 million to build and train its T5 model.

Sorcero's Language Intelligence solutions enhance and streamline a number of workflows across Medical and Regulatory Affairs.

These workflows are:

Augmenting Market Research and MSL Functions

Disseminate information in real-time to provide accurate answers to questions from HCPs and KOLs making critical health decisions.
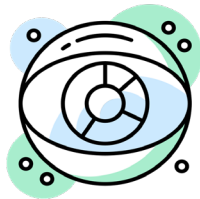
Medical Affairs Insights

Organize insights automatically in a comprehensive, user-friendly dashboard for much more efficient, impactful processing and delivery.

Post-Marketing Surveillance and Pharmacovigilance

Teams are expediting literature review up to 95%, allowing them to monitor more drugs and even shift to a more advanced, analyte-based approach.

01
Augmenting Market Research and MSL Functions

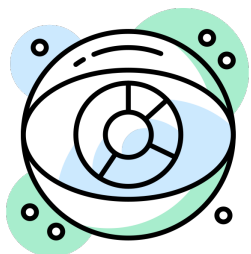Every week a vast volume of medical literature is published across disparate databases, creating fulltime jobs for teams to hunt down relevant articles to stay on top of the latest research into their marketplace, their products, and their competitors.

Similarly, in recent years the life sciences industry has shifted away from traditional methods of selling drugs to healthcare providers (HCPs), with HCPs relying on evidence-based decision-making to determine which therapeutics to proscribe to their patients. This shift has elevated the role of Medical Science Liaisons (MSLs), who must cultivate direct relationships with HCPs in order to inform them of the latest published studies and provide well-researched arguments in favor of their organization's products.

Thus, the role of MSLs requires both an encyclopedic knowledge of relevant articles and continued research into the most recently published papers. MSLs must go through the latest research across multiple data sources, shortlist the most relevant articles, annotate potential use cases, create a list of potential new use cases, identify the relevant research to bolster their position, and create presentations for HCPs.

This creates a number of points of friction. MSLs must search through multiple data sources, encountering multiple data formats and articles with inconsistent terminology and granularity of data. This not only means multiple repeated searches across different sources and terms but also leads to problems gathering the relevant passages and converting them into educational material for HCP engagement.

Sorcero's Intelligent Literature Monitoring (ILM) makes this process much simpler:

> ILM creates a single repository with specifically-tailored articles that are automatically refreshed from a smart search at regular intervals (daily, weekly, bi-weekly, or monthly).

> Sorcero's advanced analytics automatically tag ingested content, highlighting specific products, disease classes, and biomarkers.

> Sorcero's platform is designed to be flexible with both inputs and outputs, providing a single interface for literature research and engagement collateral creation, reducing the labor-intensive process of converting research into HCP engagement opportunities by an order of magnitude.

02
Medical Affairs Insights

In the course of their interactions with HCPs and KOLs, field medical teams glean a wealth of information in the form of observations, or pre-insights. These pre-insights are collected by Medical Directors, classified across a number of buckets--geographic locations, the type of insight, the type of interactions, the type of doctor, the relevant therapeutic, the relevant disease, and others-- and then entered into spreadsheets and pivot tables. This system scales poorly, becoming difficult to manage for large teams. Hundreds of hours are spent manually tagging the pre-insights as they come in, and existing solutions do a poor job of surfacing insights from the deluge of information, leading to untold missed opportunities.

As a result, insights are incorporated by fewer than 25% of MA teams according to a recent Webinar survey, and rarely quantified into metrics or KPIs in Field Medical, or recorded in CRMs. Information is often lost before it can be recorded, and once recorded it may never be seen again. Given the potential of insights to find new applications for existing therapeutics and other significant impacts, this represents an enormous oversight for many Medical Affairs teams.

Medical Affairs teams that still manually enter pre-insights into spreadsheets are missing out on the full potential of their organization. Modern technology can ingest and auto-tag pre-insights, automating the most tedious part of the workflow, and then display insights on a dashboard to make them easily visible and searchable, allowing them to be quickly actionalized.

Sorcero's Insights Dashboard allows Medical Affairs teams to reach their full potential:

Insights are quickly ingested and auto-tagged, saving hundreds of hours a month for large organizations.

Sorcero's Language Intelligence technology, user-friendly dashboard, and interface API compatibility allow users to visualize and communicate more in-depth, actionable insights across functions, locations, and therapeutic areas.

Extending the capabilities of insights generation in MA by automation, LI, and breadth of analysis results in an increased number of insights logged and raises the value proposition of the role.

Combining AI and machine learning with human intelligence and knowledge enhances team engagement, collaboration, and performance through a continuous learning and development model of insights generation, capture, and communication.

03
Post-Marketing Surveillance and Pharmacovigilance

Clinical scientists and regulatory experts are required to proactively analyze and monitor for adverse events, insufficient documentation, and knowledge gaps that could impact patient outcomes. There is widespread uncertainty among life sciences companies on how new and existing products will comply with changing regulations, but there is little room for error--running afoul of US or EU regulations could lead to immense fines and significant loss of revenue as products are pulled from the market.

It is vital to catch the first reports of adverse events in order to mitigate damage to patient health. To achieve this, experts spend a significant amount of time reading through medical journals each week, relying on complex search strings to hunt down relevant articles. These search strings may contain spelling errors that go uncorrected for months, leading teams to unknowingly miss critical information.

Adverse event reports across all disease categories are growing exponentially, with caseloads for Pharmacovigilance (PV) teams increasing 30% to 50% a year. Life sciences companies are unable to hire at the necessary pace, and scaling up new staff introduces inexperienced workers and inconsistency to the review process. Overworked PV teams are often able to review only a fraction of the relevant literature each week, potentially missing vital information.

Language Intelligence is the solution. Customers using Sorcero's Language Intelligence for PV have experienced dramatic results as measured by third-party studies:

> Intelligent search strings are able to correct for human error and oversight

> Teams using Sorcero's Language Intelligence solutions have gone from reviewing only 25-50% of the relevant literature each week to reviewing 100%

> Content is provided in a centralized repository pre-tagged, summarized, and rank-ordered, increasing productivity up to 1,000%

> Even at this increased pace, the combination of Language Intelligence and expert knowledge increases the accuracy of results to 95% from 93% from prior expert review alone.

Conclusion

Even with the billions of dollars spent by life sciences companies over the past several years, the adoption of this critical technology is unevenly distributed. Even as Research and Development has been lavished with investment, Medical Affairs and Regulatory Affairs have been left behind due to both technological limitations and institutional oversight. However, recent innovations in Language Intelligence have finally provided the technological breakthrough to bring the significant advances being made in general language AI to life sciences content.

The exponential growth of medical and clinical data presents a burden for life sciences companies. Teams are not growing fast enough to keep up, leaving them unable to fully capitalize on the wealth of information available at their fingertips. Worse, being unable to review all of the relevant information can have severe ramifications in the case of a missed report of an adverse event. The future of Medical Affairs and Regulatory Affairs will be defined by the companies that are able to turn this glut of information from a crisis into an opportunity.

With the proper technology augmenting the work of Medical Affairs experts, the "third pillar of life sciences" stands to become even more valuable to its organizaiton. It can agilely respond to new information, quickly identify insights and trends, and present a smart summary of its topline metric to demonstrate its impact. For Regualtory Affairs, Language Intelligence brings the security of reviewing 100% of relevant content--in a fraction of the time.

Moreover, Sorcero's Language Intelligence Platform is designed with flexibility and extensibility in mind. It can ingest a large and increasing number of data formats with an ingestion framework designed to preprocess them for AI use. Once ingested, it can provide advanced analytics and then produce custom outputs for specific teams. Life science companies are only scratching the surface of AI's potential, which will increase radically over the next decade. Medical Affairs sits at the nexus of a vast array of critical content, and Language Intelligence is the key to unlock the immense value latent within these exponentially-growing sources of information.

Bibliography

Choudhry NK, Fletcher RH, Soumerai SB. Systematic review: the relationship between clinical experience and quality of health care. Ann Intern Med. 2005 Feb 15;142(4):260-73

Kudumala, Aditya, Dan Ressler, and Wendell Miranda. Scaling up AI across the life sciences value chain Deloitte Insights November 04, 2020
https://www2.deloitte.com/us/en/insights/industry/life-sciences/ai-and-pharma.html

Zhang, Daniel, Saurabh Mishra, Erik Brynjolfsson, John Etchemendy, Deep Ganguli, Barbara Grosz, Terah Lyons, James Manyika, Juan Carlos Niebles, Michael Sellitto, Yoav Shoham, Jack Clark, and Raymond Perrault, "The AI Index 2021 Annual Report," AI Index Steering Committee, Human-Centered AI Institute, Stanford University, Stanford, CA, March 2021.
https://hai.stanford.edu/research/ai-index-2021

Rainsel, David, John Gantz, and John Rydning, "The Digitization of the World from Edge to Core", November 2018
https://www.seagate.com/files/www-content/our-story/trends/files/idc-seagate-dataage-whitepaper.pdf

Bendenkov. Alexander. MD. PhD. Filip Surmont. MD, and Maarten Beekman. MD. Medical Affairs' Search for Meaning Pharma Exec.com. April 25, 2018. https://www.pharmexec.com/view/medical-affairs-search-meaning-0

Carroll. Glenn. Tom Yang, Adam Volini. Annie Xu. and Seth Gazes. Medical Affairs: Driving Influence across the Health Care Ecosystem.Report. March 17, 2015.
https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us -lshc-instant-insights-medical-affairs-031715.pdf.

Coleman, Dierdre. 'The Changing Face of Medical Affairs." Eyeforpharma.com, November 22, 2016. https:// social.eyeforpharma.com/dinical/changing-face-medical-affairs.

Collier. Matthew. Richard Fu. Lucy Yin. and Philip Christiansen. Artificial Intelligence: Healthcare's New Nervous System.Publication. December 15, 2017
https://www.accenture.com/t2o171215To32o59Z__w__;us-en/_acnmedia/PDF-49/Accenture-Health-Artificial-lntelligence.pdf.

Evers. Matthias. Ivan Ostojic, Brindan Suresh, Josh Weiner. and Ann Westra. Medical Affairs: Key Imperatives for Engaging and Educating Physicians in a Digital World.Report. May 2018. https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/medical-affairs-key-imperatives-for-engaging-and-educating-physicians-in-a-digital-world.

Evers, Matthias, Brindan Suresh, Ann Westra, and Alexandra Zemp. A vision for medical affairs in 2025. June 12, 2019.
https://www.mckinsey.com/industries/life-sciences/our-insights/a-vision-for-medical-affairs-in-2025

Kapoor. Gaurav. 'Better Commercial Outcomes and Compliance with Al.' PharmaExec.com, November 26, 2018. http://www.pharmexec.com/better-commercialoutcomes-and-compliance-ai.

Kumli. Frank. Matthias Felber. and Victoria Serra Gitterman. Embracing Customer Experience in the Pharmaceutical Industry. Publication. August 25, 2016. https://consulting.ey.com/embracing-customerexperience-in-the-pharmaceutical-industry/.

Pisani, Jo, and Myrto Lee. A Critical Makeover for Pharmaceutical Companies: Overcoming Industry Obstacles with a Cross-functional

Strategy.Publication. January 10, 2017 https://www.strategyand.pwc.com/report/critical-makeover-pharmaceutical-companies.

Plantevin. Loic. Christoph Schlegel. and Maria Gordian. Reinventing the Role of Medical Affairs.Issue brief. March 05, 2017
https://www.bain.com/insights/reinventing-the-role-of-medical-affairs/.

Robinson. Robin. 'Artificial Intelligence and Machine Learning.' Pharmavoice.com, May 2018. https://www.pharmavoice.com/article/2018-05- artificial-intelligence/.

sorcero

About Sorcero

Sorcero is the leader in medical and technical Language Intelligence (LI), for Life Sciences and STEM enterprises. Its technology platform delivers a 1,000% increase in analytical capability and extracts complex insights to augment critical decision-making for some of the world's largest and most innovative pharmaceutical, diagnostic, and biotech organizations.

Contact Sorcero to learn more about what Language Intelligence can do for your enterprise: **sales@sorcero.com**

1301 K St NW,
Washington, DC 20005

www.sorcero.com

(202) 642-6447