

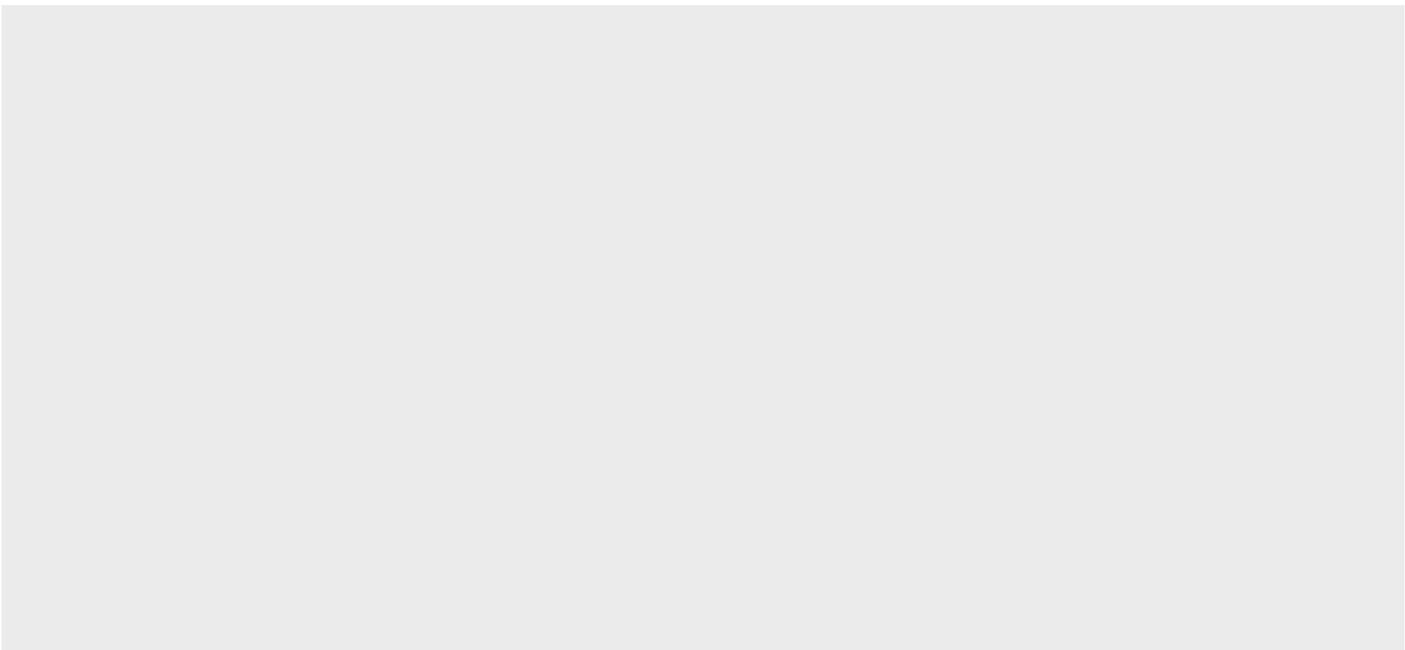
LAUNCHING NEW MEDICINE IN THE AGE OF AI: PHARMA'S QUANTUM LEAP

E-BOOK

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The importance of the Pharmaceutical industry has been thrown into sharp relief by the COVID 19 pandemic, with governments, business, and everyday people pinning their hopes for the future on the industry's development of a vaccine or treatment. But the pandemic has also exposed the industry's challenges to the public as well. Commentators and leaders, including the President of the United States, have expressed shock at how long the discovery and testing processes will take to find a vaccine or treatment. The US President famously met with top Pharma executives early in the pandemic to push them to go faster only to be rebuffed and told that the discovery process and drug trials couldn't be accelerated very much.

The truth is that the industry has long been squeezed by tight regulation, cost controls on medicines, and the necessarily long drug discovery and research process. However, there is some hope that we are on the cusp of a change across the sector. In February 2020, a team at [MIT discovered a new antibiotic](#) in record time using a Machine Learning algorithm. Could AI technology usher in a quantum leap in Pharmaceuticals? Could this new technology solve some of the industry's longstanding structural problems?

Pharma: an Industry between a Rock and a Hard Place

While the future may be rosy, the Pharma sector is facing significant challenges at the moment. The problem is that the sheer cost of bringing a drug to market is very high and many drugs fail before reaching the market. It is difficult to find accurate data on the average cost of drug development, a cost which seems to vary greatly across the industry. The Tufts Center for the Study of Drug Development puts the cost of bringing a drug from research to the market at [\\$2.7 Billion](#) and a study by JAMA Network pins the [cost at between \\$314 million and \\$2.8 billion](#). Whichever study you believe, the point is clear, it is eye wateringly expensive to develop new treatments.

These costs soar because of the nature of research and the fact that [only about half of the chemical compounds](#) identified in a study make it to Phase III of the Drug trial with the others being discarded or at best set aside for future research. The costs are also driven up by the necessary regulatory research framework in which research operates and the subsequent required reporting.

Even when a medicine reaches Phase III (the Human Drug Trial), it isn't guaranteed to make it to market. Phase III is often the most expensive part of bringing a drug to market and can last up to several years, depending on the drug being evaluated. Following this trial, medical writers must then manually go through the data and write the daunting CSR report, a process which can take months or even a year

In 2019, some industry analysts were surprised by [lackluster growth](#) numbers from some of the biggest companies in the industry. But when you look at the structural challenges in the industry, it makes sense. Soaring research costs coupled with crowding in the market (companies competing on selling the same drugs and researching the same topics) and controls on the costs of medicines; all lead to squeezed industry profits.

Many in the Industry have hyped Artificial Intelligence as a panacea that could cure the industry's chronic problems. While there are good use cases for AI technology and it can help the industry in specific cases, we need to be careful when we talk about AI and we need to stop thinking of it as magic and move to thinking of AI like any other technology, a tool that could solve a problem. Identifying the right problems to solve is critical to leveraging the right solutions with tremendous impact.

Data: Why AI Makes Sense in Pharma

Artificial Intelligence is at its' heart, computer software that analyzes data, applies a reasoning process to the data and identifies patterns in the data to utilize, explaining and collating the data as output. Admittedly, this is a vague and highly technical definition so let's look very briefly at an example. Many Pharma companies are using Natural Language Generation (NLG) to automate the writing of portions of the CSR report. Put simply, the way the technology works is that it connects to structured clinical data, analyzes it and explains the results of the analysis in written language.

Simply put, good quality structured data is the fuel on which AI technology runs. Anecdotally, the longest lasting pharma projects that we've seen take so long because of work that is required to structure and organize the data. The better structured the data, the faster an AI project can be deployed and the lower the overall cost of the project.

While challenges exist, Pharma is well positioned to leverage AI. Indeed, like Pharma itself, AI is a data-driven industry. How does Drug Discovery work? Scientists analyze data sets either to test hypotheses or to identify potential chemical reactions that could imply a pharmaceutical usage. Drug Discovery is a data-driven pursuit. Likewise, the evaluation of drugs is data-driven. When a medicine is trialed in a large group of people, researchers collect and analyze data and then explain the results of the data and analysis in written form in the Clinical Study Report (CSR). The data which fuels great Pharma companies today is the data that will fuel great AI-driven Pharma companies tomorrow.

A major challenge remains though: The more structured and organized the data, the shorter the time-to-value of AI applications can be reached. Some Pharma companies don't have a sufficient level of structured and well-organized data. Their datasets are scattered across the organization, in different silos and spreadsheets. Thankfully, this issue is being solved across the industry. Conventional database and data wrangling tools are allowing companies to organize and value their data assets at a marginal cost.

Overall, the data-driven nature of the Pharma industry sets it up nicely to leverage AI technology to disrupt itself. But what are the best use cases for AI technology?

Top AI Use Cases in Pharma Today

In early 2020, AI made headlines with drug discovery tools that helped Pharma companies comb through existing clinical data to identify compounds that could help in treating COVID-19. These headlines followed press coverage in 2019 which showed Pharma companies using AI technology to automatically write portions of the daunting Clinical Study Report (CSR) to help bring drugs to market sooner.

But AI headlines aren't anything new. The technology has captured public opinion and for better or worse we are accustomed to seeing AI plastered across the media as either a panacea or a plague. How are Pharma companies using AI and are there better use cases to start with? What about quick wins to prove that AI works and to create momentum within the organization?

1. CSR Automation

The Clinical Study Report (CSR) is based on clinical data collected during Phase III of the drug trial. The conventional approach is for medical writers to collate and analyze the data and then to write their findings into the CSR document. This manual approach is time-consuming, expensive and keeps medical writers and researchers from moving on to the next project.

Beginning in 2017, Pharma companies began looking into Natural Language Generation (NLG) software to see if it could write portions of the CSR. NLG is an AI-powered technology that, up until that time, had been best known for writing news stories and financial reports. The Value of NLG was immediately clear, but the cost of development and deployment three years ago was too high for many, and reaching a positive ROI was years out. **But the NLG sector has changed.**

[New scalable NLG tools](#) cut development time from months or years, to a matter of weeks. These newer tools also cost a fraction of their older counterparts and are built from the ground up to be secure, easy to use and scalable.

Automating the CSR can cut months off of the time to write the report. Generally, you are not going to automate the whole document with AI, instead you are going to automate the data-driven sections leaving the more creative analysis and connections

for the medical writers. Leave automation to robots and creativity to humans. A win-win proposition.

2. Drug Discovery & Development

One of the biggest challenges facing the pharma sector is to develop new treatments. At the same time, companies had hundreds of safe failed drugs that never made it to market for a number of reasons, but which costs a significant amount of money to develop. The idea behind AI-Powered Drug Discovery to address both of these challenges. That is to harness AI to repurpose existing compounds and to discovery new treatments.

Technically there are different AI-powered drug discovery approaches here. Sometimes, the approach is to look for treatments for a specific illness, for example COVID-19. In that case, you model the disease and then mine through existing data to identify correlations and outcomes at scale that might suggest a pharmacological treatment.

The technology uses the disease model to “test” the results of what will happen if the model was exposed to a range of compounds in various combinations. It throws combinations of compounds already present in the Pharma’s inventory to see what would (virtually) work. This approach has shown a lot of promise because it is directed to look for specific outcomes within a specific model. But it does require well-structured data and an approach that protects patient data if that data is being used. However, this approach has made headlines for identifying new antibiotics and helping speed up vaccine development.

The second approach is much less structured. Here, the idea is to mine through clinical data to identify patterns and to potentially identify compounds that could be repurposed to treat other ailments. The potential value here is no less high, because the technology could find potential treatments to diseases that researchers didn’t imagine were possible, using drugs that are already developed. Again, the challenge here is one of data quality.

Drug Discovery use cases in AI are almost always powered by Machine Learning technology. Machine Learning, without getting too technical, performs with the highest level of accuracy when it has the largest amount of data. This means that the Pharma company must have large amounts of data to use and that data must be well structured in well-organized databases.

3. Sales Enablement

While not specifically a Pharma specific use case, Pharma sales executives face unique challenges in terms of regulations and the sheer complexity of the products they are selling. Again, this is a use case about data. Pharma companies have data on the medicine they sell, regulations are essentially business rules and they have customer data. The challenge is that human beings aren't data processors, so just giving this data to salespeople and hoping they will use it isn't enough.

[Natural Language Generation](#) (NLG) technology analyzes the product data, customer data and identifies with regulations come into play, in order to generate a memo or script for each sales executive. This can be a quick win for pharma companies, whereby they test the software and how they work with the software on a use case that also offers them boosts in sales productivity so it's a win-win.

4. Journal Article Writing

Journal Publications are critical for pharma companies to market themselves and position themselves as thought leaders. Generally, these articles draw from Clinical Research data and repurpose the data as a means of sharing the research with other researchers, physicians, and potential customers.

However, manual Medical Writing is expensive with the average cost being about [\\$100,000 per medical writer per year](#). And, perhaps more importantly, no one likes writing data-driven text. Portions of these articles are just summaries of methods and data as well as data analysis explanations. This is very tedious and labor intensive, and it can make highly skilled people leave the company. But even if the medical writers wanted to write this content, it's humanly impossible to keep up with all the data, to write insightful (and up to date content). Hiring more writers still doesn't address the problem.

AI, however, offers a solution. Natural Language Generation (NLG) connects to clinical data and automates the data-driven portions of these reports with a click. It is, however, important to choose the right NLG tool here since some of the tools on the market are too rigid and complex to use for this use case.

5. Image Recognition in Radiology

This use case is actually broader in terms of medical and Pharma technology and is one of the most exciting AI-powered diagnosis use cases that we've seen. Correctly identifying tumors in X-Rays is incredibly difficult even for the most highly trained professionals. It's also very time-consuming and there aren't enough of these experts to expand capacity in many health systems.

AI-powered image recognition technology has improved immensely over the last five years. In the early 2010s, AI image recognition [software couldn't even recognize the difference between a cat and a ball](#), or a cat and a car. It was hopelessly bad in fact and many dismissed it's potential. It was big news in early 2012 when Google trained its algorithm to correctly recognize a cat with 70% accuracy. [Now Google can correctly identify 5,000 different species of plants and animals](#) and image recognition technology is going through a golden age.

In late 2019 and early 2020, [a raft of new stories announced that AI-powered algorithms could identify cancerous growths with a higher accuracy than a doctor](#). A [study overseen by Google Health](#) found that AI could identify cancer in breast mammograms with fewer false positives and fewer false negatives than radiologists. In China they even deployed this technology for tomographic screening of the lungs of COVID-19 patients, [where the technology performed with 99% accuracy](#).

The key with this technology is to understand that it isn't a replacement for Radiologists, it's a tool to help them and make them perform better. To use the China example, the tool was given to Radiologists and it highlighted areas of concern for them to look at. This collaboration between man and machine often presents itself in the best use cases of AI. Too often, in the public imagination, AI is a replacement for workers. But in this use case and many others, AI is better use to expand human capacity.

How to Evaluate AI Software for Pharma

We've looked at how AI is changing the Pharmaceutical industry and some of the advantages it can offer. We've examined specific use cases, but we have not shared the names of specific vendors you should consider. Instead of giving you a list of vendors in a space that is constantly changing, we think it is better to share with you a framework for evaluating AI vendors so that you can ask the right questions and make informed decisions. Here are some dos and don'ts when you are looking to evaluate AI technology.

Don't buy magic from vendors selling magic. Too many AI vendors market and sell magic black boxes. When you push them to explain their technology, they either respond with technobabble, insinuate that it's just too complicated to explain, or revert to high level marketing messages like "it will change the world". If the technology sounds like magic, it is likely too good to be true.

Do buy from vendors who know your space. Of course, you want to buy from vendors who are experts in AI not Pharma, but you need to see that they understand your industry and can talk knowledgeably about the challenges you face and the challenges of deployments in your space.

Don't buy long-term services from software vendors. In the AI space, a lot of vendors have built technology that is so complicated that only their team of AI PhDs can make it work. This won't work for you. You need to be able to see how the technology works and need to be able to understand and update the applications yourself.

Do buy Self-Service AI software. We will use an example here from the NLG space. The analysis that your medical writers do when they write a journal article or the CSR, is part of what separates you from other companies. You need to be able to control the type of analysis that the NLG tool does on data. Technically this means you need to have oversight of and the ability to write and change the business rules that the AI tech is using to analyze your data. You can't afford to call the AI vendor every time you need to make a change, it would be too expensive and too time-consuming. And, if your use case deals with patient data, the AI vendor might not be

allowed to even look at the data you are using. You need to buy software you can use. But don't stop there. You need to understand what the vendor means by "Self-Service" As an example, not all NLG is created the same and not all self-service means the same thing. You will need multiple users working on the same project simultaneously, otherwise you can't scale up and projects will be too slow. Make sure to ask vendors if their AI tools allow concurrent users to build applications at the same time.

Do ask questions about what kind of data the AI software needs. Very often in the AI space, vendors are so focused on their technology that the data their systems require is almost an afterthought. What format does their tools require? Does it integrate with specific database technologies? Will you need to build a bespoke ETL, to connect it to your data? Does it work via an API? You need to really dig into the data requirements and sometimes you need to work on organizing and structuring your data before moving forward on certain use cases.

Do buy best of breed not a do-it-all software. This relates to the topic above. If you need to organize and structure your data, you should look at database solutions not try to use something an AI company builds for you. What's more, let's say you are looking at Natural Language Generation (NLG) to write a CSR for you and you need Natural Language Understanding (NLU), AI that turns unstructured data like text into structured data, for part of the use case. You might be tempted to look at a vendor that says they do both. But the reality is that AI is not one uniform technology and there are major differences between different branches of AI. It is better to buy the best NLG technology and the best NLU technology from different vendors and to take a best of breed approach.

Do ask about Security. Don't just ask the vendors about security, ask internally as well. Depending on what data the tool will use, there may be restrictions and security certifications (like HIPPA certification) that are required. Once you understand your internal requirements, you can then go and ask the vendors to see if they offer the security you need.

Do buy AI Software that Can Scale. Proven scalability is the keyword here. You need vendors that have thousands of user building and maintaining applications every month. You need secure Cloud options that allow your teams to use the tool no matter where they are in the world and a vendor that can support the volume of users you might expect. Even if your first use case is small, you need to ask this question because if the use cases go well, then you will want to scale up the use of the technology.

How to Approach an AI Project in Pharma

What work do you need to do internally before choosing an AI vendor? The truth is that there are quite a few steps you need to take internally, and a good AI vendor will bring these points up with you early in the conversations about their technology. This is, of course, not a comprehensive list, because different AI use cases require different steps, but it should spark ideas of internal steps you need to take.

Do we have the data we need in the format we need?

This is partially addressed above. Perhaps you want to automate the CSR, in that case you need all of the clinical data in structured format. Sometimes, companies believe that they have this data but when they dig into their internal processes, they find the data isn't as structured as they believed. It is best to understand the quality of your data very early on so you can ask the AI vendors if your data will work or not. Or, so you have work with conventional data wrangling tools to build coherent databases.

Are there Patient Confidentiality issues with letting developers see the data?

Often times the data you are using for your AI projects is incredibly confidential. Even with the most confidential data there are ways to avoid breaches. For example, you could anonymize the data, or work with a solution that is stateless, meaning it doesn't keep a copy of the data. Finally, even if you are using Self-Service tools, you might need them to have specific certifications or for some of their staff to sign specific agreements. The truth is this varies a lot depending on use cases and even companies, so it is best to do your homework before talking to a vendor.

Will there need to be a change management process implemented?

As we have discussed, in people's imagination, AI can be seen as something very different from what it truly is. If you are expecting your teams to be using AI every day, you will need to go through a change management process with them to ensure adoption of the tech and to allay any concerns.

Who are the stakeholders internally for this project?

AI projects often cut across departments involving more than the line of business with the use case in mind. Every department will have different concerns and questions. Before speaking with Vendors, it is best to speak with all of the stakeholders to understand what their hopes and concerns will be around the project. You can use those conversations to build a list of questions and a matrix to evaluate vendors.

Do we need a POC? If so, what are we trying to prove?

Oftentimes, the reflex is to start with a POC (proof of concept) with one or two vendors to evaluate the technology fit for your use case. But you need to take the time to understand what you are trying to prove with the POC. Are you trying to prove that the technology works? If so, there are other ways to validate this. You could speak with analysts or customers of the vendor.

Are you trying to prove that you can use the tech yourself? This is a good goal of a POC, but you will need to make sure you are clear internally about what you are trying to prove and why. We would suggest coming up with a list about what success looks like. This list will also help you ask the right questions of vendors.

Do I have a budget?

Budget is always a touchy subject, but you get what you pay for. If you ask a small AI company for a free POC, you should not expect something that functions because they don't have the time to invest fully in it. We've also seen AI companies charge six figure sums for POCs, we would certainly not recommend that for a POC. However, you should expect some investment in a POC.

Conclusion

AI software has the potential to fundamentally change the Pharma industry and could address some of the structural challenges the industry is facing today. But we can't be drawn into the narrative of AI as a panacea, this damages the AI industry and could damage Pharma companies as well if they simply throw money at AI vendors to fix all their problems with magic solutions.

The truth about AI is that it's not magic, but it is incredibly powerful computer software. But something strange happens in the public imagination when we talk about AI. [Author Pamela McCorduck](#) called this phenomenon the AI effect. She argues that once we understand how AI works, we say, "oh that's not real AI, it is just computing" and we continually push the definition of "real AI" into the realm of Science Fiction. This AI effect means that people are looking for AI to be magic and are happy to dismiss as "not real AI" AI that they understand. The AI effect leads AI companies to enter into a "AI Magic Race" where they try to one-up each other in explaining how magic their tools are.

In this guide we've stuck closely to the science and left the science fiction for others. The goal has been not just to explain the huge potential of AI in the Pharma space, but to go further offering you tangible examples of how AI is being used right now and finally to give you a framework to evaluate perspective AI vendors. All of these insights have been based on our team's experiences working with customers in the Pharma sector and beyond. We hope the insights have been helpful to you and we are very happy to speak with you and your team about AI, use cases in pharma and how you might address specific use cases.

Appendix

About the Authors



AX Semantics is a AI-powered, Natural Language Generation (NLG) software company with its roots grounded in content and storytelling. Our sophisticated, yet easy to use SaaS-based software makes automated content generation accessible to customers of all sizes, is used widely within the e-commerce, business, finance and media publishing sectors. Available in 110 languages, AX Semantics works with more than 500 customers, including globally recognized brands like Deloitte, BASF, Ebner & Stolz, Porsche, and Nivea. AX Semantics was named one of the world's world's top five providers of Natural Language Generation platforms by Gartner, and a top emerging company in the NLG market by Forrester. AX Semantics is changing the way content is created, published and viewed. Our software allows thousands of users to successfully automate text within two days, and gives people the space to develop and nurture their creative originality. Headquartered in Stuttgart, Germany with an additional office in Sunnyvale, California, AX Semantics is a privately-held company backed by Airbridge Equity Partners. Follow us on social at Twitter, LinkedIn, Instagram and Facebook, or learn more at <https://en.ax-semantics.com/>.



Nituno (London) is an B2B Consultancy dedicated to helping B2B software companies understand their markets and sign enterprise deals, while helping clients choosing the right vendors. Nituno was founded by the former Head of Sales and Head of Marketing in a B2B AI company. The marriage between sales and marketing is at the heart of Nituno. Nituno believes that tech companies need to practice what they preach and adopt new technologies to help them scale faster.