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# Our Industry: Technology driven or driven by technology

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## ABSTRACT

A certain level of innovation and technology is present in all industries. In fact, it has become necessary to facilitate growth, productivity and competitiveness. With the focus on different technologies across industries, we are faced with some challenges regarding the adoption and implementation of them. Where do we stand compared to other industries? As Pharmaceutical companies and CRO's are Research and Development organizations, it is imperative that we keep up with technological trends and use them to drive our outcomes.

This paper explores the timeline of our industries ability to adopt and implement trending technologies compared with other industries, showing how these trending technologies have gone from conception to growth. It will deep dive into a few of these technologies and how they should be playing an impactful role in our industry and how we can use technology to drive us forward.

## INTRODUCTION

We live in a world where technology is constantly evolving; end-users are either keeping up or being left behind and having to experience greater learning curves in the future. This is true for a variety of different industries, where if they are left behind, it could result in major loss of profits and may require much larger investment to catch up later. All departments within a typical pharmaceutical (pharma) firm are adopting and implementing new technologies, from research and development (to speed up new drug development and help develop breakthrough treatments), manufacturing (automate machines and processes) and sales (digital pharmacies).

All aspects of a clinical trial have seen some form of digitization to date to increase quality, accuracy and gain faster time to market, but we still have a long way to go; while other industries such as the financial sector has had lower barriers to entry for new technologies and has already earned a top spot in digitization. This paper considers the trending technologies by reflecting on the past, our progress (how we have embraced new technologies and those that are already playing an impactful role in the industry) and what we can look forward to in the future.

## OUR HISTORY WITH TECHNOLOGY

### TRIAL PROCESSES

About 15 years ago, the monitoring of patients relied heavily on subjective evaluations and face-to-face consultations, for example:

- Adverse events went unnoticed and unrecorded due to adverse event severity often being misjudged, because of patients not reporting the symptoms accurately or prior to needing medical attention and they may have been unable to notify anyone when a crisis occurred.
- In order to monitor and collect the paper case report forms, site visits would have been required by the Pharma company representatives and the subject would have to be monitored at the site itself; resulting in resources being needed such as nurses, doctors, monitors etc. which can be time consuming and expensive.

Over the years, there has a been a gradual implementation of technologies that allows patients to be monitored from the comfort of their homes and for reliable objective measurements to be collected remotely at any time.

### DATA MANAGEMENT

The pharma industry has witnessed revolutionary digitization which resulted in the addition of FDA 21 CFR part 11 compliance, about 20 years ago where many paper heavy processes such as paper Case Report Forms (CRF) etc. were replaced by innovations such as Electronic Data Collection (EDC) systems, electronic CRF's, electronic Informed Consent (IC) forms, and electronic health records. This small set of regulations gave the pharma industry the needed support to move trials to electronic systems and platforms [1].

These electronic processes have led to the following efficiencies:

- Cleaner and validated data, leading to better accuracy and quality.
- Version-control and access-control of data and supporting documentation.
- Clearer and more concise audit trials.
- Faster and easier issue tracking.
- Minimal need for subjective human intervention, minimizing the chance of human error significantly.

#### BIOSTATISTICS AND PROGRAMMING

Prior to the widespread adoption of electronic data capture and documentation, statisticians and programmers were usually situated in the same office due to the unique challenges of not having pre-approved methods to transfer electronic data and supporting documents securely.

One of the challenges was that Tables, Figures and Listings (TFL) for Clinical Study Reports (CSR) were paper-based, which programmers had to print and collate manually and then these documents had to be sent to the regulatory authorities via couriers; which resulted in lengthy timelines. Additionally, the documentation for validation of TFL's was completely paper based, with no electronic means of tracking, which wasted quite a lot of resources and time. Inefficient communication added to this challenge, since the use of teleconferencing and videoconferencing was still in its infancy.

The introduction of electronic data capture, validation and electronic submissions, has revolutionized the way trials are conducted. Due to technological advancements in communication (Skype, Google Hangouts etc.) and networking capabilities (Virtual Machines, Cloud storage etc.), a global team of programmers and statisticians can work on the same trial from different geographical locations.

Throughout all the departments of a pharmaceutical company there were a few key barriers to adoption of new technologies:

- Skepticism and unreliability – Finding reliable technology to replace the old manual processes was not an easy task, proving the value of the technology was even harder.
- Time to make changes and adjust – Due to pharmaceuticals being a fast-paced industry, adapting to change was a time consuming and tedious effort with regards to training.
- Budget and cost implications – Generally budgets are kept under careful consideration and the initial cost of implementing new technologies might have been excessive.
- Regulatory requirements – Our industry is highly regulated and only approved processes and systems may be used.

Regardless of the barriers faced, there has been a gradual increase in adopting and investing in the implementation of new technologies within the industry.

## CURRENT ADOPTION AND IMPLEMENTATION

#### THE INTERNET OF THINGS

"The internet of things" (IoT), is a system of interrelated computing devices, mechanical and digital machines, objects, animals or people that are provided with unique identifiers and the ability to transfer data over a network without requiring human-to-human or human-to-computer interaction [2]. To put it simply, IoT refers to a vast number of "things" that are connected to the internet so that they can share data with other "things" such as IoT applications, connected devices, industrial machines and more. Internet-connected devices use built in sensors to allow the collection of data; certain data points can trigger the device to act on an event.

In the pharma industry, one common and affordable real-world IoT which is being implemented with the least barriers to adoption is dedicated Smart Wearable devices and monitoring apps.

Industry specific uses:

- Detection of early signs of serious medical events – potential life-threatening events can be detected prior to the adverse event requiring hospitalization or emergency intervention.
- Real-time automatic alerts concerning medically significant events – when a patient has an asthma attack, the device will send an immediate alert to the relevant medical professionals.
- Notifications to encourage treatment adherence which reduces non-compliance and improves quality of data – if the connected device picks up that a subject has missed a scheduled dose, it will send a reminder to the subject via the device and the mobile application; if the subject has still not taken action on these reminders, it will alert the relevant pharmaceutical representatives.

- Remote check-ins with medical professionals and pharma representatives allow active monitoring of the subjects' progress and potential issues – The subject can check-in to unscheduled "digital visits" via the mobile application as needed, reporting any issues and progress more frequently than it would be possible during scheduled site visits only
- Assess the effects of experimental treatments in real-time – The effects of the experimental drug on the subject e.g. heart rate can be monitored from the minute the scheduled dose was administered
- Wearable and ingestible devices that are used in conjunction with each other gives detailed analysis of the subjects' conditions – relying on subjective evaluation of symptoms can be subject to inaccuracies, these devices can reveal the true nature of the symptoms, allowing for more accurate data

We can identify another real-world example of IoT in pharma which is personalized medicine which tailors' treatments to match individual patients' physiology and conditions. One-size fits all treatments no longer serve patients in certain therapeutic areas. Precision treatments are developed considering the genetic make-up of individual patients. This is still very much in the early stages of development.

Practical implementations and investments that have recently made headlines in pharma news:

- Cohero health is using a BreatheSmart device, which is an adapter that is attached to an asthma sufferers' inhaler and it connects and reports data remotely. The device creates a log entry each time the inhaler is used, which makes it easier to detect when the patient is non-compliant, and it sends the alerts to the connected parties. The device captures and analyzes data about the patient's lung and airway functions, this gives a good indication on whether the disease is improving, staying the same or deteriorating. The greatest advantages of this device are that it is more personalized, there is fewer need for in-office visits and thanks to the quick accumulation of data among many patients, ongoing product improvements are a possibility. The goal of this device is to reduce the likelihood of further hospitalization and readmission, this gives doctors and patients a new sense of ownership over treatment and health care outcomes. [3]
- Pfizer and IBM are collaborating on a project called "Project Blue Sky"; they are working on a smart spoon which Parkinson's disease patients will use in order to gather data will detect tremors. The objective of this technology is to measure patient's symptoms and the impact on their daily lives [4]. Symptom diaries are an outdated practice that no longer gives us an objective view of the patients' set of symptoms. This spoon is a new, more convenient way to collect data that may aid in symptom treatments and shed new light on the disease.

According to the world's leading research and advisory company, Gartner; collecting and putting data to good use could save the industry billions of dollars a year, which is enough to fund the entire R&D budget of a large pharma company [5].

IoT adoption in other industries

Financial industries have adopted IoT as a full suite service, for example in banking services. According to PWC's 6th annual digital IQ survey, it is one of the top 10 sectors investing in IoT solutions [6] and according to Absolute Markets Insight, IoT is expected to grow exponentially due to increased automation and the demand for optimized solutions [7].

Factors that make IoT an important asset to any data related industry:

- It provides accessibility to information from all devices, any time and from anywhere.
- It improves communication between all electronic devices connected to a network.
- It saves time and money, because data is transferred over the network that the devices are connected to.
- Generally, digitization and automation help improve processes and reduces the need for human intervention.

Factors that make IoT difficult to adopt:

- The more data that the connected devices collect, and the more data is shared between these devices, the more potential there is for confidential data leaks or theft.
- The huge numbers of collected data needs to eventually be dealt with, managing the data from all the devices is a massive challenge.
- There is a possibility that a bug in the system or software may affect all the connected devices and corrupt them.
- There is myriad of connected devices to choose from and so many manufacturers, that the lack of international standards of compatibility for IoT can make it difficult for the devices to communicate.

An additional barrier for the pharma industry is that it is heavily regulated, and mistakes often have more dire consequences, and can incur serious liability, so the industry is very cautious about adopting unfamiliar technology. When choosing third party IoT partners, pharma companies need to be vigilant and confirm that they have the necessary processes and procedures such as digital signatures, role-based controlled access etc. for safeguarding sensitive data. As much as smart devices have many relevant uses, any device that administers medical treatment or reports patient data is likely to fall under The Health Insurance Portability and Accountability Act (HIPAA), thus strict security regulations must be established for this innovation. Although there is value of IoT in the pharma industry, there are many standards and security regulations that still need to be established.

Although the IoT concept has been around since the 1990's, it has experienced various growing pains in all industries. Technically, IoT is estimated to be "born" between 2008 and 2009, when the number of connected devices became greater than the world population [8].
The power of IoT, data collection and analytics provide new ways to manage, monitor and improve the most vital processes within data-driven industries. IoT has already made a notable impact in the pharma industry as well as other industries even though the innovation is still in its infancy. It represents the next evolution of the internet, using its ability to gather, analyze and distribute data that is then turned into information, knowledge and ultimately wisdom.

**AUGMENTED ANALYTICS**

Augmented Analytics (AA) automates data insights by utilizing Machine Learning (ML) and Natural Language Processing (NLP) to automate data preparation, insight generation, insight visualization, enhanced analytics, data sharing and business intelligence. It focusses on a specific area of augmented intelligence, using ML to transform how analytics content is developed, consumed and shared. These capabilities are expected to advance rapidly to mainstream adoption in data preparation, management, modern analytics, business process management, process mining and data science platforms. [9] [10]
Although there is evidence that both AA and Artificial Intelligence (AI) adds value to the pharmaceutical industry, there is an argument made by Pamela Spence, sector leader for life sciences from Ernst and Young (EY) global; that Artificial Intelligence has not really arrived in the pharma industry, she believes it is more augmented intelligence, where technology and algorithms are used to interrogate data and suggest decisions. She noted that the big difference is that pure AI computers work without human input, whereas augmented intelligence use algorithms, data processing and machine learning to assist the human decision-making process [11].

The current focus of the pharma industry is shifting more towards predictive analytics and big data. Due to the increase in data volumes, it is becoming more complex and resource intensive to analyze, it makes it challenging to identify the most relevant findings. The field of data analytics has evolved significantly over the years and due to the need for data scientists to analyze big data, the gap was identified for augmented analytics. This is done by linguistic and statistical technologies to break down big data into more usable, smaller chunks which results in smart subsets of data that are easier to work with and base decisions on [12].
A unique challenge for the pharma industry is that AA would require validation processes to check that these algorithms work properly. Different forms of validation will have to be done, because the results may come with a lot of scrutiny from regulatory authorities. Validation such as running parallel market research can be an option to verify the outcomes of the data. The conclusions must be accurate and robust.

To apply AA directly to pharma processes; could this be the future of Table, Figure, and Listing generation as well as Health Authority Questions and queries? Software such as Tableau and SAS are tools that support analysis, but they do not automate the process, programmers and analysts are still needed to make sense of the data. The application of augmented analytics is far more powerful than standard SAS and Tableau. However, SAS Viya may be the solution that the pharma industry has been waiting for. SAS Viya is a cloud-enabled, in-memory analytics engine that provides quick, accurate and reliable analytical insights. Its elastic, scalable and fault tolerant processing addresses the complex and analytical challenges of today, while effortlessly scaling for the future [13].

AA adoption in other industries

The Retail industry has implemented AA in creative ways. Through user accounts at online stores and loyalty/account cards at physical stores, they collect data on what, when and how frequently purchases are made and what methods of payments are used. With this data, retailers can send personalized promotional coupons and provide personalized shopping experiences. The biggest industry that has adopted AA, has been Marketing and Advertising; by tracking real-time browsing via social media platforms such as YouTube, Facebook, Instagram etc. organizations can tailor advertising to individual users taking into consideration their individual preferences.

Leading players of the global Augmented Analytics market include Salesforce, SAP, Microsoft, IBM, Tableau Software, Microstrategy, SAS, Qlik, Tibco Software, Sisense, Information Builders, Oracle, Yellowfin, and Thoughtspot [14].

Advantages of the implementation of AA in data-driven industries:

- Presents real-world data in a clear, optimized, unbiased and accurate manner, which leads to confident decision-making. This results in timely and accurate actions.
- Significantly reduces time-consuming data analysis processes in order to identify necessary insights only, this is specifically useful for big data.
- Inefficient, time-consuming and expensive third parties may be eliminated for companies that rely on daily research and reporting. This results in greater control and ownership of data. This is more apparent for the Sales, Marketing and Advertising sectors.
- Augmented analytics tools are easy to use, the procedures, algorithms, and methods are available to the average professional user, without having knowledge of data science or needing any formal training to use. The dependency on data scientists, analysts and technical programmers may be reduced for standard analysis. Data analysts and scientists' talents can be used more efficiently, freeing up their time to focus on other tasks, making better use of resources.

There is sufficient evidence to indicate that all roles and business units within a data-driven industry can reap the benefits of implementing AA. Lower barriers to entry would allow for faster adoption of this technology, which would allow industries to harness the power and full potential of AA's reliable, efficient, and optimized capabilities for complete, accurate and meaningful insights.

With the impact that currently implemented technology is already making, the realization of how fortunate we are to be living in a time where science and technology is improving our lives in many aspects is quite evident. The technologies that are already part of the digital environment, have encouraged further innovation. Future technologies are both overwhelming and exciting and have the potential to shape the future in ways that cannot yet be comprehended.

## OUR FUTURE WITH TECHNOLOGY

### QUANTUM COMPUTING

Quantum computing (QC) is a type of non-classical computing that operates on the quantum state of subatomic particles that represent information as elements denoted as quantum bits. The concept of Quantum Computing in digital data processing is revolutionary, that it is based on the fundamental principles by which nature operates, i.e. quantum mechanics. The parallel execution and exponential scalability of quantum computers means that they excel with problems too complex for a traditional approach or where traditional algorithms would take too long to find a solution.

Experts believe that QC services and software will play a significant role in the pharmaceutical industry, with emphasis on the drug discovery process. Predictions are that it will be one of the first and the most valuable implementations thereof.

Possible real-world pharmaceutical implementations [15]:

- By utilizing AI and QC, detailed interpretation of diagnostic images and the results will improve exponentially. Efficient ML can train a quantum computer to identify abnormal findings more precisely than the human eye can.
- Personalized treatments are a possibility with data-informing predictive models and quantum computer resources. Medical professionals can select individually-suited therapies based on predicted treatment responses while considering patient specific characteristics.
- The therapeutic area where QC is predicted to make the biggest impact is Oncology. By allowing physicians to compare all possible approaches this efficiency will allow radiation to be pointed directly at the target, thus reducing side effects and increasing effectiveness of the treatment. Quantum computers would allow faster and more precise radiation therapy.
- It could be used to model and simulate molecular interactions at atomic levels to accelerate time to market for new cancer-treating drugs. QC can accelerate and more accurately predict the interaction of proteins leading to new methodologies.

- Big data research and machine learning is most likely to advance rapidly with real world functional quantum computers.

Examples of Pharma at the forefront of QC:

- Roche have announced that they have a task force preparing for "the big wave". This task force was set up some time ago, monitoring the field, developing collaborations and piloting early applications [16].
- According to Morgan Stanley, Amgen is conducting its own QC experiments [17].
- Biogen have teamed up with Accenture labs and 1Qbit, to potentially improve treatments for neurological and neurodegenerative disorders by exploring QC solutions for chemical simulations [18].

This will give these organizations a great advantage once the technology is ready to adopt.

At this point in time, it is too early to assess the exact value of the implementations of QC. It is still unknown when QC will be available for daily use in medicine and research. Until then, we can speculate that its impact will be beyond measure.

Potential benefits of Quantum Computing [19]:

- Faster drug discovery and production – Significant time is currently spent on drug research and development, sometimes up to 10 or 12 years to bring it to market.
- Reduced cost of the drug development process – a big percentage of revenue currently goes towards R&D.
- More precise and accurate drugs – the possibility for human error is significantly minimized.
- Fewer side effects associated with treatment – QC can simulate all possible outcomes.
- Cures for currently incurable diseases and potential to treat many more diseases.
- Better understanding of human physiology on a molecular level.

Other industries that will gain from this advancement are the Information Technology, Automotive, Financial, Insurance and Military. In the Aerospace industry, Airbus is seeking to use QC for data storage and sorting, satellites imagery analysis, and the development of new materials for its aircraft. They are preparing by establishing a research team to study the potential applications of QC [20].

According to Gartner, most organizations should prepare by learning and monitoring the innovation from 2022 and get ready to utilize QC from 2023 or 2025 [21].

What can we do to prepare for the Quantum Leap?

- Research and learn about QC and the applications thereof by building prototype applications.
- Find all the areas in your line of business that could benefit from QC by identifying potential real-world scenarios to apply it to.
- Establish relationships with technology companies manufacturing Quantum computers e.g. IBM and D-Wave.
- Develop your talent pool - the most important step.

Until we can leverage the power of QC, its implementation will remain experimental.

**DIGITAL ETHICS AND PRIVACY**

There is no official definition of Digital Ethics, but Rafael Capurro defined it as "The impact of digital Information and Communication Technology (ICT) on our societies and the environment at large." [22] Considering this definition, we may conclude that digital ethics and privacy cannot be deemed a stand-alone technology. It has a direct impact on all the other trending technologies discussed in this paper.

As the digital economy is growing, wherever data collection and sharing is involved, there will be new security, ethical and privacy challenges. As much as we can see the extensive benefits of implementing these technologies (Internet of Things, Augmented Analytics and Quantum Computing), their impact needs to be explored.

Factors that impact digital ethics and privacy:

- The first and most necessary consideration when collecting and sharing data; is consent. Whether it is informed consent in a medical context or end-user license agreements for internet services, it remains an important step in the protection of the individual and the privacy of data [23].

- A potential risk of big data may be the lack of transparency thereof. Big data equals big value, it does not just mean more data; it has the potential to be extremely valuable when it has been refined into significant insights via augmented analytics [24].
- Given that there are many different stakeholders involved such as people, time, money and technical resources in the collecting, managing and analysis of data, each person involved has an obligation to focus on what good can come from it. When the focus of using these technologies is solely based on financial gain, the issue of trust arises and the opportunity for positive impact will be discredited.

The pharma industry is one of the best examples of maximizing the use of data and technology for the greater good of humanity. When we use the available resources and technologies ethically, to better leverage the wealth of data available, there is potential to achieve the seemingly impossible. Even though it is agreed that patient data should be safe and secure, privacy and security should never be a barrier to optimal utilization of data and technologies.

Keeping in mind that the aim is to improve future treatments and patient lives, we cannot ignore the overall benefits from research being done using sensitive data. The European Medicines Agency (EMA) policy 0070, which is a policy on the publication of clinical data for medicinal products and human use [25]; has motivated creative innovation to de-identify and anonymize documents and data, which minimizes safety and security concerns, allowing trending technologies to be adopted and implemented with confidence.

According to IBM, the Life Sciences sector is most susceptible to cyber-attacks, which comes with a higher risk than other high-risk industries such as Financial Services. The pharma sector requires connectivity, visibility and the easy flow of information and while digitization may help escalate operations, theft or fabrication may incur significant losses. If any sensitive information is compromised, it can be detrimental for a pharma company's trust and reputation [26].

Digital ethics and privacy in other industries

The advertising industry via social media is under heavy scrutiny regarding digital ethics and privacy due to data leaks and privacy violations. Companies have been collecting financial, biometric, behavioral, biographical and medical data which can be summarized and analyzed, sometimes without the owners' explicit consent. This personal consumer data is often shared with third parties as well. Since there are no clear ethical frameworks in place for digital technologies, this makes it difficult to initiate any criminal proceedings. The IT industry and other tech giants often bypass restrictions by providing unclear privacy policies and often take advantage of existing loopholes in legislation.

The current digital economy makes this an opportune time for the relevant regulatory authorities and governance entities to pro-actively discuss the development of a common framework for the utilization of digital technologies. These trending technologies require new ethical standards and privacy regulations and it should not be left to legislation to force the industry into compliance. It is the responsibility of each organization to establish best practices.

As the ever-changing digital economy advances, there is an ever-increasing number of redundant electronic devices (e-waste) and the forecasts are not reassuring. Ethically speaking, organizations should be mindful of the impact on the environment and digitization plans should include potential eco-friendly solutions. The challenge we face is to find innovative methods to balance the value of technology vs the consequences of technological advancement.

There are certain key questions that must be asked when considering the impact of digital ethics and privacy on the trending technologies:

1. How does implementation of these technologies influence ethics and privacy?
2. Is the overall impact positive or negative?
3. Is data being inadvertently collected without the owner's consent?
4. Is a safe and secure digital environment being maintained?
5. Are the end-users adhering to ethical conduct while utilizing these technologies?

This paper has not even touched the tip of the iceberg regarding digital ethics and privacy. There is a myriad of scenarios that have not been discussed and so much more can be said about the impact of trending technologies on digital ethics and privacy, that it cannot all be properly covered in a small section alone.


## CONCLUSION

Digital transformation in the pharmaceutical industry offers opportunities to revise its entire business model, improve its processes and increase its receptiveness to customers. The volume of data being processed by pharmaceutical companies is showing no signs of slowing down, which means that the industry must be proactive and be at the forefront of building core internal digital capabilities; moving beyond our traditional IT functions as we know them, in all aspects of the business. By investing in new technologies and finding different ways of working, we can ultimately gain competitive advantage through speeding up the drug development and approval process.

Being innovative and keeping an open mind is key to achieving both operational efficiencies and appeasing all shareholders. Through strategic collaborations with other data and technology-driven creative industries, the collective talents, skills, knowledge and other resources pave the way to achieving a common goal. In our mission to progress as a technology driven industry, adopting and implementing new technologies as we discover their value, we must harness the full impact that technology has on our industry.

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