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Advanced Analytics in the Pharmaceutical Industry

How big data and advanced analytics are revolutionising the prospects of companies within the pharmaceutical industry and why they have been so slow to adopt.

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10/12/2020

At a Glance

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The data revolution:

How technology and advanced data analytics can revolutionise the pharmaceutical industry.

2

How companies are using data:

Cleaning in place processes, to maintenance, commercial insights and customer service AI, and data analytics are all transforming business processes.

3

Implementing industry 4.0:

The challenges and opportunities companies face when embracing advanced analytics.

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Conclusion:

Data use is accelerating change and with it comes opportunities. For pharmaceutical companies it is increasingly becoming a case of ‘adapt or die’.

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The Data Revolution

Digital technology has transformed the world of business in a very short time. While it creates opportunities, many businesses are struggling to adapt their models to keep pace.

The world of business is undergoing a new revolution. Industry 4.0 technologies are sweeping all before them as digital transformation sweeps all before it. However, innovation is changing the game faster than many businesses can keep up. Companies need to adopt data driven business models to understand the market, predict the future, reveal fresh insights and optimise costs across all processes.

This is particularly true of the pharmaceutical industry in which the marketplace is becoming increasingly dynamic, innovative and competitive. Demands are changing and pressures on costs and profit margins are growing. Advanced analytics will be increasingly vital for firms which want to keep pace with a changing environment.

The pharmaceutical industry has been relatively slow on the uptake, as a report from PwC highlights[1]. Innovation is stymied by a lack of technological infrastructure, risk averse culture and shortage of expertise. However, such are the pressures of the digital economy that companies are making the move. Those early adopters are showing the way for the others and piling on more pressure to those who are still reluctant to move. In this digital world, it will be a case of adapt or die, with late adopters finding it increasingly difficult to compete in the digital marketplace of the future.

In this report, we will assess the importance of embracing advanced analytics in the pharmaceutical industry and how companies are going about it.

[1]Advanced Analytics Fuel Tomorrow's Commercial Strategy: https://www.pwc.com/us/en/health-research-institute/assets/pwc-pls-advanced-analytics-report.pdf

Data Analytics Going Forward

1. **100** Zetabytes, or **50%** of the world's data will be stored on the cloud by 2025. (CyberSecurity Ventures)[1]
2. **87%** of provider executives and **83%** of Health insurance executives say they are using or plan to use data analytics. (Source Society of Actuaries)[2]
3. Most Pharma Companies Have Yet to Bridge the Gap from Experimentation to Scale: (McKinsey)[3]
4. Advanced Analytics Could Improve EBITDA by **45%** to **75%** over the next decade (McKinsey)[4]
5. COVID 19 Prompts Rise in Cybercrime (Europol)[5]

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The Rise of Data Analytics

If steam powered the industrial revolution, data is providing the fuel for the digital.

The amount of data available to organisations has exploded in the last few years. The next five years are likely to see an even bigger explosion in data quantity. IDC has warned businesses to expect 175 zettabytes of data by 2025, a 61% increase on where we stand today with the cloud holding as much data as is held in data centres[1].

From artificial intelligence to machine learning, data mining, predictive analytics and process automation businesses are harnessing digital technologies to boost their performance across all commercial areas. However, this is a revolution which is unevenly applied.

Adoption varies between industries and companies. While some are powering into the future others are lagging behind. This is creating a digital gap between the early adopters and the slow movers and that is also having an impact on how businesses are being valued.

A report from Palladium Digital says most private equity investors say digital is high on their agender, and are gradually starting to adopt methodologies for factoring digital adoption into their investment decisions[2].

They will look at how far a business has progressed with digital integration compared to its peers. If a business has fallen behind it will affect their valuation and may even cause them to avoid a business altogether, even if the current balance sheet looks good. Such is the digital gap, they will feel, that it will soon become almost impossible for that firm to compete.

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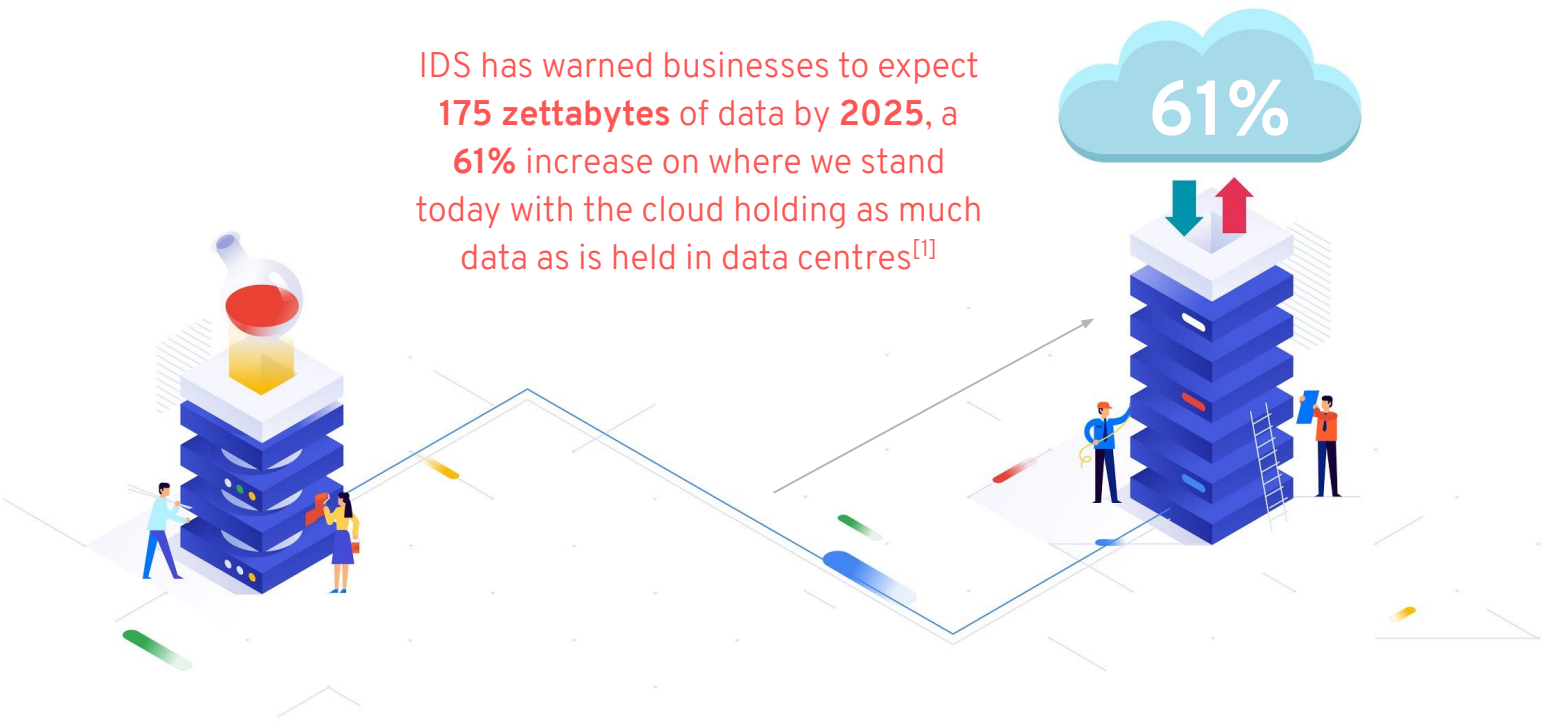


Slow on the Uptake

The pharmaceutical industry has been slower than most in making the change. As elsewhere, part of the reason comes down to fears of risk, cost, a lack of expertise or infrastructure. However, integrating real time data into the health sector is particularly challenging. Records can often be months old and arrive in unstructured and digital unfriendly format. The challenge of accessing that data and integrating it into business operations is much higher than in other data driven businesses which regularly connect with the web.

Data analytics will be vital for pharmaceutical manufacturing companies as they seek to cope with these various commercial pressures.

It helps at both ends of the funnel; reducing costs by optimising operations and increasing revenue by using data insights to identify new opportunities and maximise profitability.

They are using data in a number of ways including the acceleration of drug discovery, cleaning, maintenance scheduling, improving the efficiency of clinical trials and much more. Once again, a gap is opening up between the digital haves and have nots. Those which have successfully identified opportunities and implemented digital transformative products are surging ahead of those which have not.

How the Industry Is Changing

In the digital age standing still is not an option. It is a case of adapt or die. As such, companies of all kinds are assessing their operations and identifying ways in which digital technology can help them achieve their objectives.

According to a 2019 survey from IDC Insights, 94% of respondents in the US and UK agreed on the importance of applying advanced analytics to data across their industry[3].

For example, AstraZeneca, Bayer, Celgene, Janssen Research and Development, Memorial Sloan Kettering Cancer Center, and Sanofi recently announced a new data sharing initiative. Dubbed Project Data Sphere[4], it will allow companies to share historical cancer research data in a globally available database provided by a software as a service provider.

The push to adopt advanced analytics becomes even stronger with the arrival of COVID 19. The pandemic has created challenges for industries of all kinds. The pressure is on to make the best strategic decisions about the future of the company.

Data will be crucial in making certain key decision makers have the most accurate and up to date information at their fingertips to help them make effective choices which safeguard the future of the business. The benefits of doing so can be transformative to a company's fortunes.

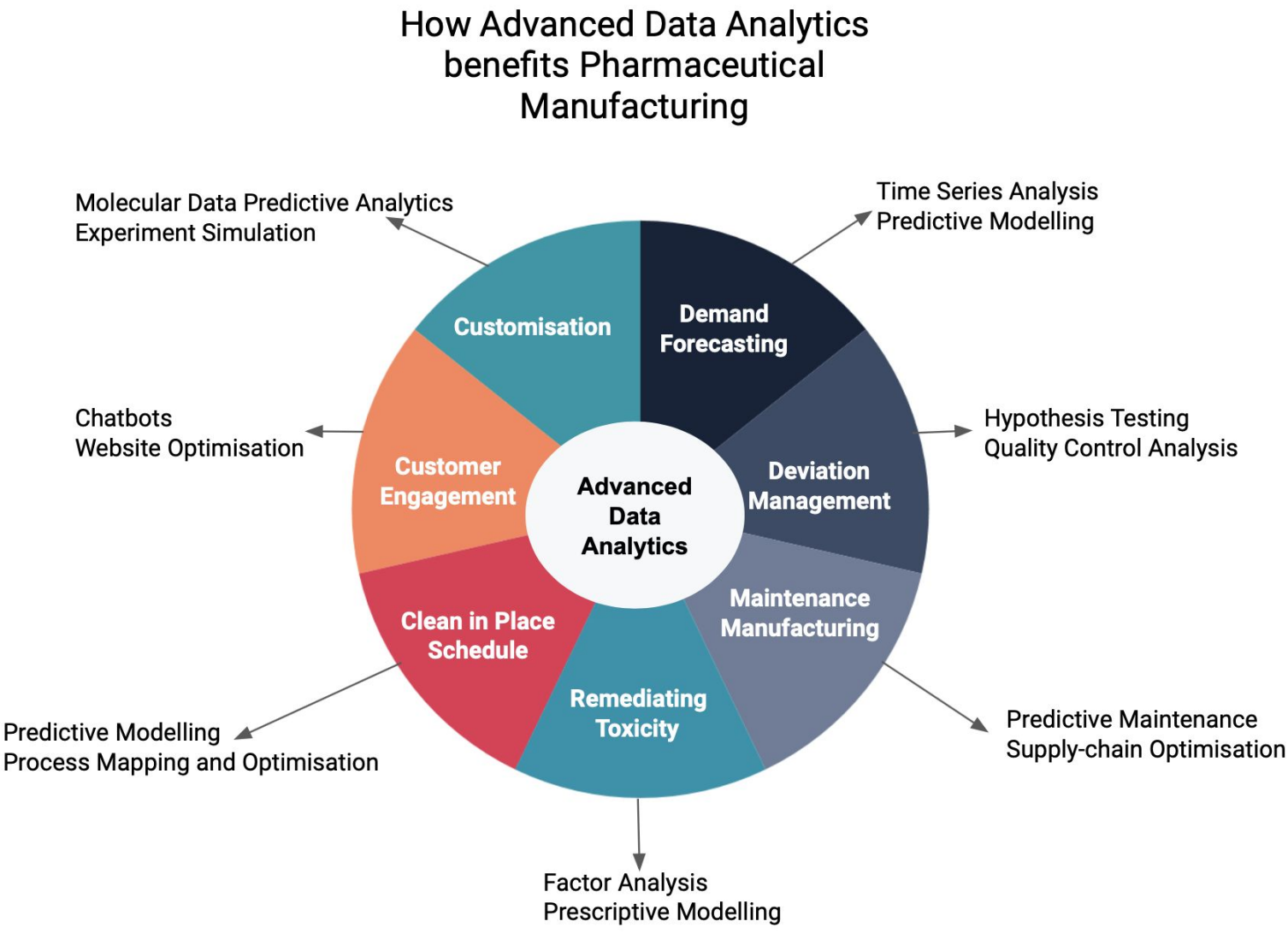
McKinsey & Company estimates the impact of advanced analytics can be as high as 15 and 30% of earnings before interest, with the difference rising as high as 70% over a ten year period[5].

The scene is set for a period of rapid digital transformation within the industry. Companies understand the need to change and the technology is increasingly available to facilitate the change. Even so, challenges remain in terms of infrastructure, personnel, security and culture. To truly move into the digital future, firms will need to understand what they want to achieve, what the technology can do and how they can benefit.

How Pharmaceutical Companies Are Adopting Advanced Analytics

After a hesitant start pharmaceutical companies are starting to apply advanced analytics to revolutionise their manufacturing arms.

Pharmaceutical companies have long relied on data to identify patterns, put theories to the test and understand the effectiveness of treatment. Digital technology and data science is allowing all these processes to become more efficient, effective and affordable. Manual processes are becoming automated while enhanced analytics reveals granular data which sheds new light on business operations.



Customer Engagement

One of the most immediate gains in customer engagement comes from chatbot technology. Companies across all sectors from finance to healthcare are using automated chatbots with natural language processing to help improve their customer service. According to a report from Gartner Chatbots could soon replace 85% of customer interactions[6].

In 2017, MSD Italia launched what it described as the sector's first chatbot which answers physicians' questions via Facebook. The app grew out of their activity on social media where they found themselves engaging with customers and starting conversations. AI chatbots were the logical next step[7].

Others have followed. In 2018 Sanofi launched a chatbot for the French market called Nina aimed at people with sleeping disorders[8]. The system provided people with simple advice to help their condition such as switching the colours on mobile devices to warmer, 'sleepy' colours during night time.

Health Tap, meanwhile, created an interactive Facebook chatbot which helps people quickly find out what may be wrong with them and recommended a treatment. If the system can't answer a query it connects the user with one of over a hundred doctors worldwide who will provide an answer within 24 hours[9].

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As the technology becomes more effective, public acceptance is growing. Research from Digi Health shows that most patients are willing to use chatbots for minor issues which do not require a physical examination[10].

The system also provides a pharmaceutical company with a goldmine of information about what their customers are looking for and common ailments. Over time, this information can be fed into machine learning systems to identify those patients most likely to be high risk or who might fail to respond to treatment.

Cleaning Schedules

Chatbots represent the low hanging fruit for technologies which have the potential to transform the industry. With the rise in digital technology, firms are becoming increasingly adept at capturing digital assets which power additional insights across many different areas of operations.

One of the most important is the clean in place (CIP) schedule. Cleaning between batches eliminates impurities in the product and helps to ensure compliance and quality.

However, it is important to optimise this process as much as possible. Cycle times need to be minimised to avoid wasted resources and time. The aim is to reduce time taken without compromising compliance or standards, but this is can be complex.

Using conventional existing techniques companies find it difficult to identify CIP cycle time inefficiencies. The safe approach will inevitably include some degree of overcleaning and accept inefficiencies.

Data can improve CIP cycle efficiencies and reduce the time needed for each run. In addition, it can enhance the cleaning process and reduce the risks of error.

A case study on Pharma Online demonstrates how a major drug company did exactly that[11].

Cleaning Schedules

To shed more light on the CIP the company had to see where it was spending time on CIP and use the data to develop process models across different circuits using all the data available to them. This helped them establish a clear view of the existing model and identify improvements.

Using data analytics, the team developed models for each of its CIP units. This enabled them to identify processes which were excessively long and involved over cleaning.

The team relied on metrics including percentage of time per mode, total water use and peak conductivity in each CIP cycle. Using this, they compiled a report to quantify potential savings and propose improvements to cycle times.

Using this data they succeeded in reducing CIP dryer cycle time, with administrative control rather than a feedback closed-loop control, increase the efficiency of the CIP operation, enable visualisations of durations and troubleshoot delays, and identify short term opportunities for process improvement.

Deviation Management

Pharmaceutical companies must adhere to strict manufacturing environments, compliance and approval processes to keep operations under control. However, this can be a considerable challenge. Deviations from processes can impact the safety and reliability of products and imperil the regulatory compliance of products. This can have a direct impact on costs, health, safety and the reputation of the company.

Because deviations are unintentional it often goes undetected which is one reason why it can be so dangerous and difficult to manage. Teams will need to identify the root causes, assess the potential for damage and rectify the problems.

Advanced software and analytics can accelerate all these processes. They can automate the process of identifying deviations ensuring they are spotted at an earlier stage. Automated systems can enable companies to resolve problems more quickly and put processes back on track.

Remediating Toxicity

Data analytics can provide insights into toxicity, identifying hotspots, tracking progress and pin pointing remediation techniques. Biotechnology company Numerate, for example, builds predictive analytical models which make forecasts on a range of metrics including toxicity, metabolism and absorption of drugs. This can help a company identify the best candidates to take forward for trials as well as optimising drug use.

Data can also assist in reducing pollution caused by the pharmaceutical industry. Toxicity and pollutants caused by pharmaceuticals is a constant problem. Chiral pharmaceuticals have been linked to serious diseases including cancers, making remediation of toxicity an increasingly important priority. Current remediation efforts focus on sorption and sonolysis biotransformation and advanced oxidation processes (ozonation and photocatalysis).

Improved data use can shed more light on a particular problem and provide insights which can help firms reduce their impact.

Maintenance and Manufacturing

Market pressures are increasing the importance of the manufacturing process. Aside from the wider pressures to reduce costs, the move towards smaller and more frequent drug launches adds to the opportunities for efficiency improvements at the manufacturing stage. Small gains here can contribute to considerable savings overall.

Pharmaceutical companies are examining the use of data in the manufacturing process, with smart factories expected to bring dramatic improvements.

A survey by Bain & Company found that pharma executives expect smart, connected factories to produce savings of 20% or more. They forecast a 17% reduction in costs related to inferior quality and a 15% decline in the cost of converting raw materials into drugs and a 14% increase in delivery reliability[12].

Some of these developments are relatively easier to implement and can deliver quick gains. Efficiency savings from these can be reinvested to help develop harder to implement and more advanced solutions in the future.

15%

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14%

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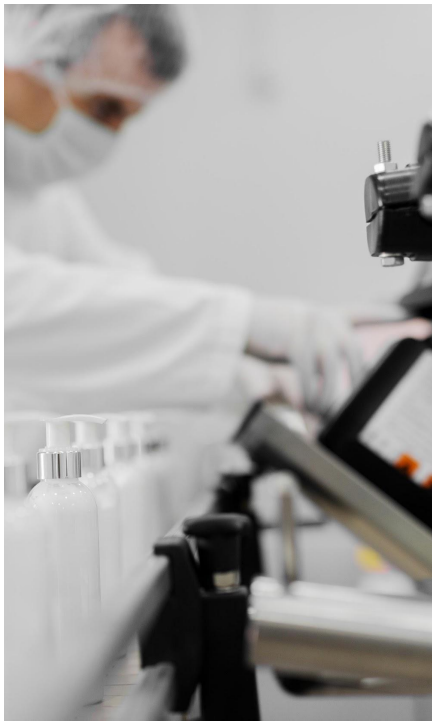

Maintenance and Manufacturing

For the short term, therefore, pharmaceutical companies are looking at options such as:

- **Production Performance management:**
  Real time data from manufacturing equipment produces an overview of the entire production system.

- **Cloud based networking:**
  Companies of all kinds are moving to the cloud. Its enhanced capacity allows for big data management and can give managers an overview of data and processes from any location in the world. It also improves collaboration between multiple teams and helps improve coordination.

- **Global traceability:**
  A more effective analytical view of their global supply chain allows companies to optimise logistics and drive down costs.

- **Advanced analytics for predictive analytics:**
  Data from sensors identify breakdown patterns. This allows companies to predict the performance of parts and optimise maintenance. The early warning gives production teams a change to minimise downtime.

- **Advanced changeover support:**
  Movement of teams on the shop floor when reconfiguring machinery has an enormous impact on downtime. Technology such as video simulations or VR classes help operators follow a predefined procedure and accelerate the time taken for changes.

In the future they are working towards:

- **Predictive quality management planning:**
  Recognises patterns linked to quality problems which helps teams avoid defects and react faster and more effectively to problems. Identifying the root causes of problems helps teams address issues in a more timely manner.

- **Augmented and virtual reality machine maintenance:**
  Virtual reality and augmented reality are being used across the process. They can add to the real time information at the hands of staff and also help communicate data in real time.

- **Blockchain in supply chain for quality inspection:**
  The blockchain has a potentially transformative impact on how data is stored and transferred. It is immutable and allows for greater capacity in data handling.

Implementing Industry 4.0

How can companies go about bringing the next generation of advanced data capabilities into their organisation?

Pharmaceutical companies are increasingly opening themselves up to the opportunities on offer from digital transformation. However, understanding its value is one thing, successfully implementing it is another. Each organisation will have to address a series of important questions such as:

- **How can we improve the quality of data collected?**
- **How can we improve business operations?**
- **Can we integrate new technologies into existing processes?**
- **Should operations be controlled in house or should we choose a third-party provider?**
- **Can we ensure data security and regulatory compliance?**

The answers to those questions will determine how successfully firms integrate advanced analytics technologies into manufacturing processes.

Data Quality

Transforming a business into a data driven enterprise starts with improving data quality. This is particularly challenging for the pharmaceutical industry where it can be difficult to obtain real time data in a usable format. However, developments in the health sector are contributing to an explosion of data generation from sources such as research and development process, retailers, patients and caregivers. However, quantity doesn't necessarily translate to quality.

Advanced analytics systems have the capacity to store, manage and transform data in such a way that it can collate and derive usable insights from highly complex data sets and present it in an accessible format for key decision makers.

This has the potential to improve the overall quality of processes at every stage from research to manufacturing, trialling and distribution.

Some of the most promising avenues include:

- **Predictive modelling of biological processes can help drugs to become more sophisticated and widespread.**
- **By leveraging available clinical and molecular data predictive analytics could be used to identify new candidate molecules with a high probability of being successfully developed into drugs.**
- **Trials can be monitored in real time giving superior granular detail about performance. This can highlight potential problems at an earlier stage and reduce the occurrence of adverse events.**

A company which wishes to transform itself into a data driven enterprise, therefore, needs to have access to high quality data, which can be integrated into the organisation and there is considerable progress.

Culture and Attitude

Addressing culture within a business is vital if a company is to adopt industry 4.0 technologies. Although things are changing the biggest impediment to change is a fear of change and a feeling among companies, that they lack the expertise and infrastructure to integrate advanced analytics effectively.

Companies will face a challenge of integrating new technology with existing technology and systems. Attitude, culture and expertise are all obstacles, so these must be overcome.

The most successful companies adopt a detailed step by step process which puts the fundamental building blocks in place which enable them to facilitate the transformation.

This starts with attitude. The adoption of digital technology is a business transformation as much as a technological challenge. The entire business will have to adapt to ensure its systems can cope with the coming changes.

Next firms must invest in people with the right skills and capabilities to help you move towards digital manufacturing. This process will include the use of third party organisations and providers

The rise of digital technology places an increased emphasis on the importance of partnerships. Digital transformation is driven by innovative and high performance small companies capable of delivering advanced technological solutions. Identifying best in class partners and providers will be vital. For this firms can learn from the example of other industries.

The one advantage of being relatively slow moving in the uptake of digital technology is that the pharmaceutical industry can look to the examples of other sectors, which have already progressed a significant way down the path of their own transformations. These offer a valuable learnings for any company wishing to explore the same path.

For example, the entertainment industry uses big data analytics to help inform customer choice; the financial sector harnesses data to highlight operational improvements, enhance customer engagements and identify investment opportunities.

In the aviation industry early adopters such as Delta Airlines have seen enormous benefits. The company's share price has soared over recent years, until the unexpected intervention of COVID 19. It attributes much of its success to a comprehensive adoption of data analytics which permeates throughout operations and has transformed airline operations, improving services and customer engagement.

For example, a $100 investment in airport baggage systems allowed it to use data to transform baggage handling operations improving performances and identify key trends to help it identify the causes of baggage mishandling errors and improve process times.

In House or Outsourced

The use of partners shines a light on a pressing question: whether to outsource this process or keep it in house. Both have advantages and disadvantages.

By outsourcing, you can leverage expertise and technological infrastructure you might not possess internally. You can employ a team of experts with the capacity to understand the technology and apply it to your team.

The downside of outsourcing is that you relinquish control to a third-party provider who may or may not be up to the task. You understand your business needs and if you have a sufficiently sophisticated in-house team, you'll be able to craft a truly bespoke solution designed specifically around you.

Third party providers will vary in terms of the quality of service they can offer, and to what extent they can provide bespoke solutions designed specifically for your requirements.

The use of a third party partner also potentially opens you up to security risks if their own infrastructure is not up to date.

Organisations will therefore have to assess their own operations and adopt the right approach for them. While larger organisations might over time have developed their own extensive and highly advanced internal functions, this might not be possible for other smaller and mid-tier operations.

They will benefit from adopting either a fully outsourced or hybrid model to leverage the expertise and capacity from specialist organisations.

In short there are three options to choose from.

In house:

Data capabilities are built in house from the ground up. This will help to retain control and develop a company culture in which data analytics is at the heart of operations from the ground up. It helps companies control costs over the longer term and brings in talented individuals with the skills and experience required to deliver superior performance.

The down side of this approach is that it requires a substantial up front investment, requires planning and has a long lead in time. Companies will have to develop specialist in house teams and recruit expert individuals from what is still a limited talent pool and purchase state of the art technology.

Looking to the future this also lacks flexibility. Resources and functionality could be constrained by the infrastructure you have in place which will take time and be expensive to replace. In an environment in which new technology is being introduced continually new systems can quickly become outdated.

Outsourced:

Choosing a third party provider, on the other hand allows firms to leverage the skills and expertise of a specialist company. Services are more flexible and can grow with the company and as the wider technological environment evolves. Start up costs are lower, with the firm leveraging the infrastructure of their partner companies.

However, you will be fully dependant on those third party organisations and will not develop the internal skills and culture to capitalise on digital transformation. You will need a closely managed service agreement to ensure the partnership meets its objectives. Equally, if you have entered into a long contract you might incur penalties if you wish to end the relationship early.

Hybrid model:

A best of all worlds approach in which you partner with some third party organisations for some operations. Others are built in house.

This offers more control over data insights and the ability to start building a skilled in house team. Services are more flexible, with those which are not needed easily discarded in order to optimise costs. Over time it could be a stepping stone to evolving your own fully in house functionality.

However, firms are still dependant on third party organisations. It offers less control over analytics capabilities than a fully in house approach and may slow the development of internal expertise and understanding.

Understanding Security

Industry 4.0 also brings a number of potential security vulnerabilities and compliance issues. By processing more data firms inevitably open themselves up to the risk of cybercrime.

The growth of digital technology has been accompanied by a growth in cybercrime. Gartner predicts damages related to cybercrime will top $6bn globally by 2021. As healthcare and pharmaceutical companies become more adept at capturing, sharing and analysing data, they are also becoming increasingly attractive targets for cybercrime. Criminals are drawn in both by the quantity of highly sensitive personal data these organisations process, but also a perception that defences may not be as developed as other more mature industries such as the finance sector.

According to Deloitte pharmaceutical companies are being targeted more frequently than used to be the case[13]. Criminals are looking to steal trade secrets, personal data and drug formulas and, as digital technology takes hold, all of these are potentially more vulnerable to attack.

The use of third parties also increases the risk exposure. Any organisation which connects with yours and shares data can present a potential weak point to your security. No matter how robust your own internal cyber security provisions are, they can be compromised by a partner organisation without significantly robust protocols.

According to a report from the Poneman Institute[14], 61% of breaches are caused by third parties and 44% of organisations describe those breaches as 'business changing'.

As the owner of that data you will retain the responsibility for any data lost even if it occurs as a result of a failure with the partner. As such it is important to perform digital due diligence on any third parties to ensure their cyber security provisions are sufficiently

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Conclusion

Although the pharmaceutical industry may have been slower than others on the uptake of advanced analytics, firms are investing significantly to embed data science into their operations. Some organisations are at the proof of concept stage, some are adding data science to key operations and some now see advanced analytics as a critical element to their strategy for the future. It's no longer a question of 'if', but 'how' firms should embrace data & digital technology.

Many firms have assessed the risks of standing still outweigh the risks of adoption and this has recently led to fast adoption and desires to scale-up and scale-out their analytics capabilities. Many organisations have yielded new insights to drive efficiency, but several have encountered challenges along the way.

Challenges such as a lack of expertise, inconsistent data standards, poor (or indeterminate) data quality, gaps in infrastructure and sub-optimal business culture have slowed adoption, or even derailed some initiatives. These challenges will therefore have to be solved if organisations are to be successful in their data and digital transformation. Those which have been successful have followed some common steps which has enabled them to lay good foundations, work with the best providers and minimise their exposure to risk.

While every organisation will be different it is possible to learn from others who have been successful already. The following eight steps will be useful:

- **Assess existing operations – structured baseline tools can help**
- **Engage widely and share successes – do with, rather than do for**
- **Get the right technology – migrate to a common data platform; consistent tools**
- **Pick the right outcomes – yield, quality, cost, time and organise data processes around those**
- **Improve data quality – standard approaches, common processes & platforms, QC notifications and alerts**
- **Abstract analysis from operations – share data analysis outputs widely**
- **Adopt the right learning model – centres of excellence and third-party support structure**
- **Ensure security, transparency and privacy – being agile and gaining digital benefits whilst maintaining compliance**

This represents a useful template on which pharmaceutical manufacturers can base their digital transformation projects. By laying the groundwork and taking a measured step by step approach, firms can ensure a successful and sustainable implementation which ensures they will be on the right side of the digital revolution.

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