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Whitepaper

UNLEASHING DIGITAL POTENTIAL IN THE PHARMACEUTICAL INDUSTRY

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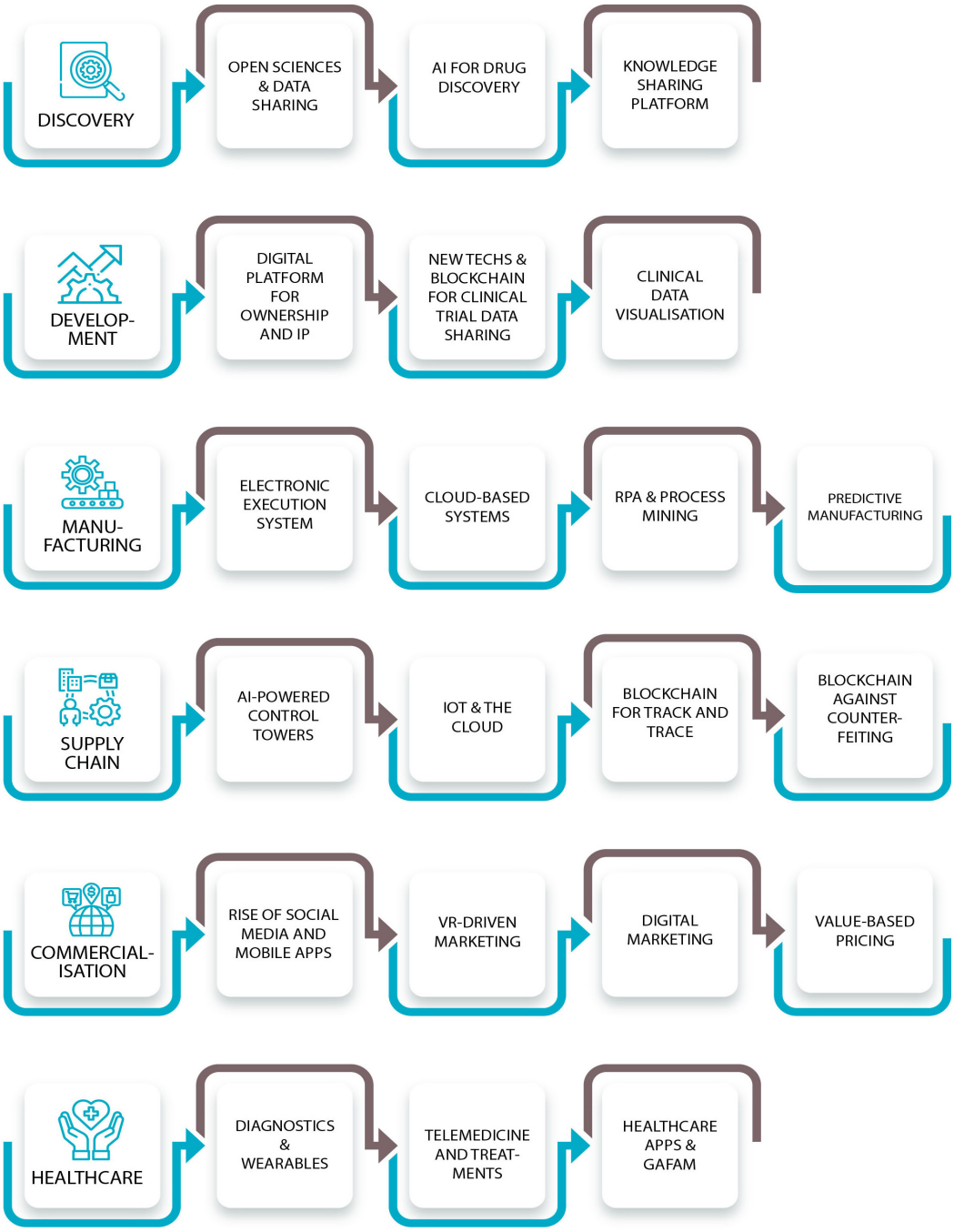
Digitalisation in the Pharmaceutical Industry



As part of their core strategies, our clients see clear benefits in digital transformation whether it is for optimising costs, reducing time-to-market or creating new business models and patient journeys.

Evaluating paths, mobilizing the organization toward its digital journey, prioritizing projects and implementing them in highly regulated environments are some of the key topics where Avertim helps turn strategies into operations.

Hervé Lefébure, CEO

Content

1

Introduction

The pharmaceutical industry is currently undergoing an unprecedented transformation as digital technologies permeate all aspects of the classical pharmaceutical value stream.

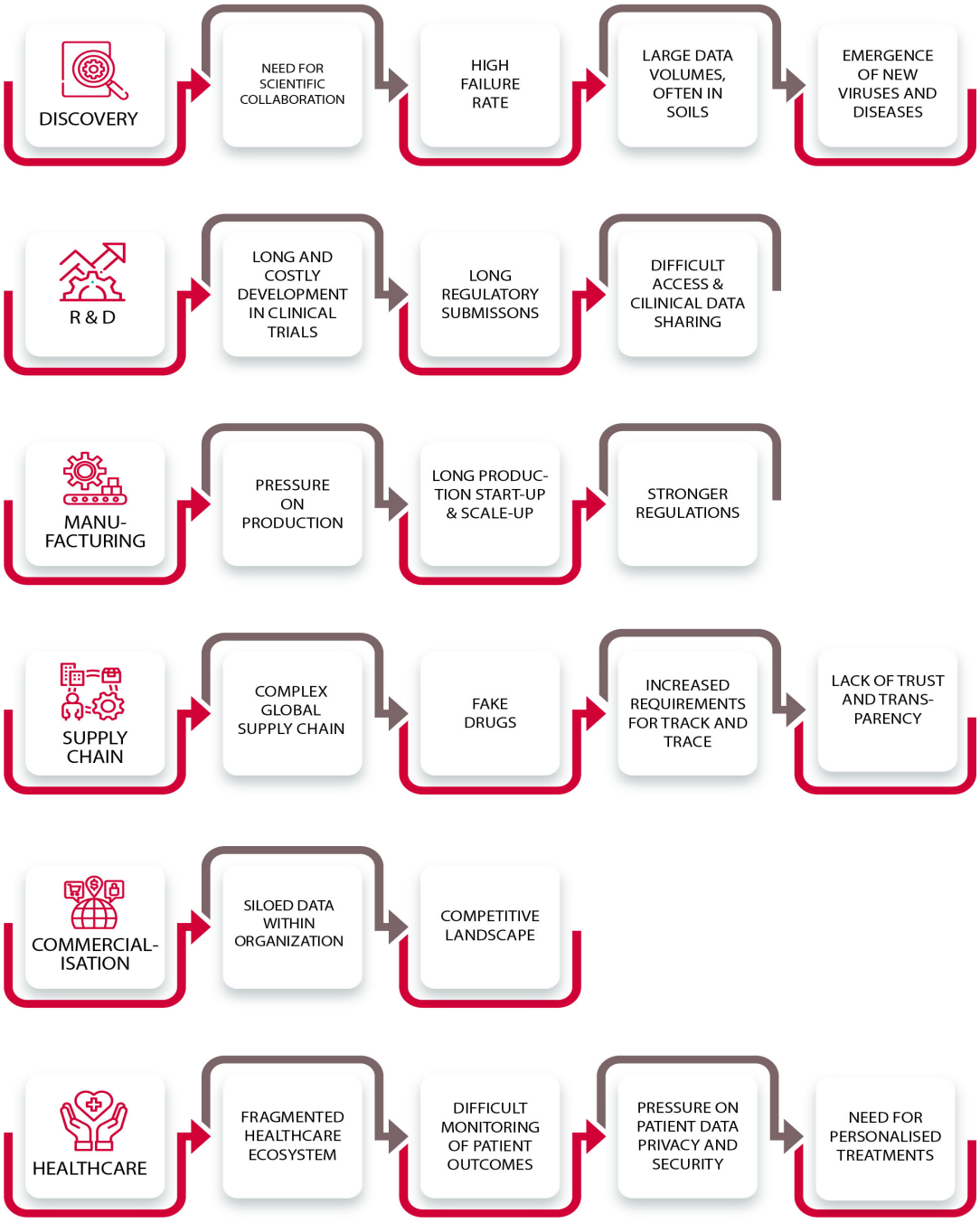
In recent years, an increasing number of players in the pharmaceutical industry has come to realise that there is considerable potential in harnessing digital technologies along the value stream to increase success rates, drive efficiency gains and thereby reduce costs. As a highly innovative science-based sector, pharmaceuticals can benefit greatly from the integration of common digital tools as well as novel technologies like big data, advanced analytics, process mining, cloud computing, smart devices, artificial intelligence (AI) and blockchain technologies. With improved data sharing, collaboration, automation and management along the whole pharmaceutical life cycle, these technologies can offer new ways to discover, develop, manufacture, and deliver drugs and patient treatments.
The SARS-CoV-2 induced COVID-19 pandemic has made it clear that traditional analogue ways of working in the pharmaceutical industry are inadequate to overcome such global health crises within socially and economically acceptable time frames. Long vaccine and drug development timelines – sometimes more than fifteen years from initial research to market entry – must be reduced by all means.

Pharmaceutical companies like Pfizer, BioNTech, J&J, Moderna, AstraZeneca, GSK, Sanofi have been working hard to get a COVID-19 vaccine to the market in a time frame as short as 12 to 18 months. This ambitious timeline can only be achieved by streamlining research and production, parallel work streams and maximising data sharing between all the partners involved.

In this article, we will highlight typical challenges along the pharmaceutical value chain: discovery, development, manufacturing, supply chain, commercialisation, and healthcare.

We explore several digital applications which can be offered as of today. Some technologies and use cases presented are already being widely deployed in the industries, whereas others are still in the pilot stage. Many other technologies promise revolutionary applications which seemed too far away to be covered in this research.

Challenges within the Life Cycle



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Issues along the life cycle

The discovery, development and commercialisation of a novel drug is an arduous, costly and time-consuming venture with a high failure rate; especially as research and clinical development activities suffer from long timelines, with clinical trials being a main driver of costs and risks of failure. The probability of success through all clinical phases until approval for all drugs and vaccines is only 13.8%, according to a recent **MIT** study, with high variation by therapeutic area such as oncology with a 3.4% success rate.

Once a drug has been developed and successfully tested in clinical trials, manufacturing and operations become time-critical steps. As drug margins are usually higher in the first commercialisation years, scale-up times must be shortened. With the increasing age of a drug new market competition emerges which in turn creates the need to reduce production costs.

Other main drivers of costs along the pharmaceutical value chain are the necessary yet challenging regulatory requirements which may differ between international markets. A **New Drug Application** (NDA) to the US Food and Drug Administration (FDA) often contains more than 100,000 pages.

Regulations tie in with supply chain activities, as increased requirements for tracking and tracing are coming into effect. Supply chains are often long and complex and depend on partners which do not always work in transparency.

During the commercialisation phase, companies are navigating through an increasingly competitive patent landscape. They need to adopt the right medical and marketing strategies to ensure commercial excellence, engage with healthcare professionals and provide medical information through multiple channels.

> “The discovery, development and commercialisation of a novel drug is an arduous, costly and time consuming venture with a high failure rate.

At the patient’s side, the improved health access gives rise to personalised medicine; creating the need for robust privacy management of sensitive medical records, something that is hindered by the fragmentation of stakeholders in the current healthcare ecosystem.

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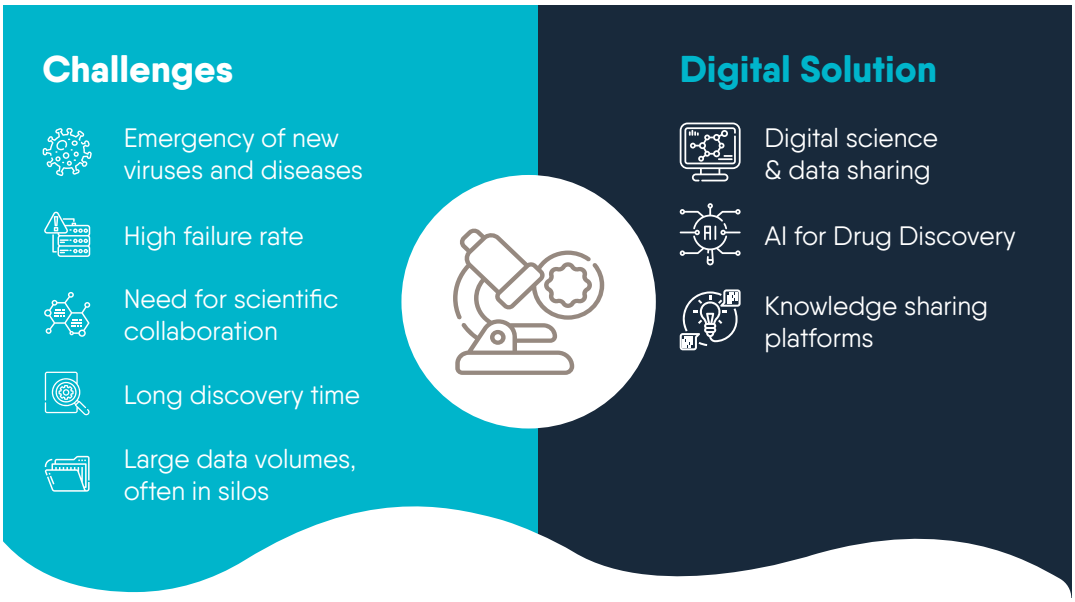
Digital applications along the value chain

- Discovery
- Development
- Manufacturing
- Commercialisation
- Supply Chain
- Healthcare

Discovery



The time-consuming process of drug discovery is being facilitated by recently emerging technologies such as biomolecular knowledge-sharing platforms, Artificial Intelligence (AI) and open-science. In parallel, firms and organisations are partnering, sharing information or working in open-source models to develop and implement such technologies aiming at advancing healthcare.

Knowledge sharing platforms

Recent biotechnological innovations and the rise of bioinformatics are bringing new tools for drug discovery such as gene therapies, in vivo genetic engineering techniques (CRISPR-CAS) and tailor-made drugs for personalised medicine.

Platforms to share and analyse biomolecular (genomic, proteomic, metabolomic) data are therefore increasingly needed. These knowledge-sharing platforms pave the way to a new way of working.

With biological and chemical building blocks and equipment becoming cheaper and more readily available, this technology is attracting more and more users. The combination of biomolecular sciences with big data analysis and predictive algorithms can facilitate the development of novel drugs.

AI for drug discovery & medical decision making

IBM has been training its artificial intelligence **Watson** to improve medical decision-making for cancer treatment. Big data and AI can greatly help researchers to predict how the pharmaceutical form and application (i.e., pill, tablet, capsule, liquid or cream) of a novel drug will influence its effect on the patient.

Predictive algorithms and AI, together with language recognition software, can be used to skim unstructured databases, such as published studies and proceedings, for relevant information with minimal effort.

Open-science and data sharing for R&D

The growing open-science movement and decentralisation technologies are aiming at creating the required trust and transparency to unlock cross-collaboration amongst network participants in the drug development process.

Immutable blockchain ledgers and smart-contracts can offer the ability to integrate the necessary controls and governance while linking to the right authorities. Start-ups like IKU are creating bio-R&D open-source marketplaces specifically for that purpose.

Avertim Reference Case

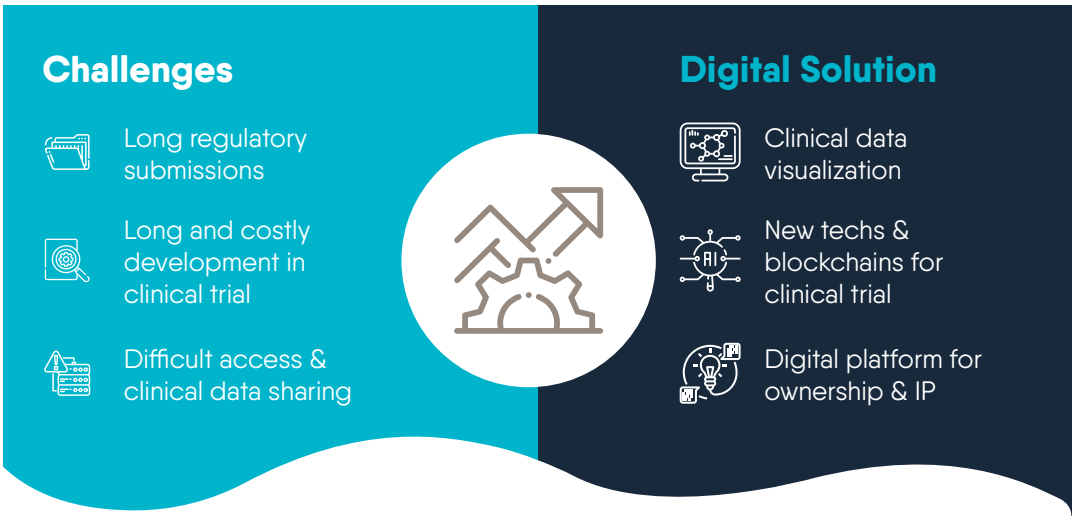
Digital in discovery

Since 2008 the European Union is providing funding to support the development and application of new digital technologies in pharmaceutical research. The Innovative Medicines Initiative (IMI) program has already led to several successful Public-Private-Partnerships.

In one of the IMI projects, nine pharmaceutical companies, as well as a dozen tech providers and research institutions joined forces in a consortium to establish a machine learning platform that will make it possible to learn from multiple sets of proprietary data while respecting their highly confidential nature.

Avertim has been supporting the consortium by facilitating the management of the alliance, the general execution of the project work streams as well as the coordination with legal, technical and scientific communities.

Development



In the development stage, digital solutions are, among others, transforming the way clinical data is stored, secured and shared during trials. Some examples of technologies being used are blockchain, data visualisation tools, and digital platforms for intellectual property and data collection.

Blockchain for clinical trials data sharing

Clinical research is a core activity within the drug development process and requires pharmaceutical companies to engage patients across multiple clinics and test centres, in order to collect and store data and monitor all events and deviations from the study protocol in a reliable way.

In scientific studies, especially in clinical trials, all data points and protocols need to be documented in a logbook. New tools and technologies can solve the challenges of maintaining these documents, keeping track of changes, securing data against forgery, and allowing for access and incentivising sharing data with partners which traditionally do not act transparently.

Numerous companies are, for example, piloting the use of blockchain technologies in clinical trials such as the twenty-nine consortium entities behind the IMI project **PharmaLedger.**

> With blockchain, complete history of changes can be immutably tracked to enforce controls and streamline adherence.

With blockchain, the complete history of changes can be immutably tracked to enforce controls and streamline adherence. The distributed ledger architecture makes collaboration more trust-worthy and transparent by design. Informed consent files and personal information can be traced in an anonymous and privacy-protective way during trials.

New technologies and data visualisation for clinical validation

The independent, not-for-profit organisation **PHUSE** counts various pharmaceutical companies and service providers that are exploring the many use cases of new technologies in clinical research. One of them is the use of data visualisation for clinical data.

The risk-based approach to Monitoring (RBM), introduced by the Food and Drug Administration (FDA) a few years ago, now allows companies to provide scientifically founded monitoring solutions as alternatives to 100% source verification of clinical data. Data visualisation applications can help.

Digital platform for ownership and intellectual property

Intellectual property protection in the form of filing and storing patents and protecting proprietary data is a slow and expensive process which is challenging to monitor at global scale. Current intellectual property systems have hindered cross-collaboration between pharmaceutical companies and individuals, and hence, the rate of development and innovation.

Present-day systems do not make provision for a multitude of participants to provide valuable input into the development process. New digital technologies can offer a platform to protect intellectual property better, facilitate payments and royalties, and incentivise models of collaboration.

Avertim Reference Case

Digital in clinical development

Avertim is supporting a major vaccine manufacturer to digitalise two clinical trials processes: the collection of the subjects' informed consent before enrolling them for a study and the collection of the primary reported outcome once subjects have received a vaccination.

The digitalisation of the informed consent is piloted with a new eConsent system, using smartphone-like devices to replace the paper form. In the current paper-based process the rights are provided to the subjects (withdrawal, data privacy, ...) often via long text form explaining the purpose and the risks of the trial.

The use of a digital tool helps to increase subjects' comprehension by providing pictures, an interactive glossary, audio and videos, as well as increasing subject engagement and participation. Avertim has been involved in supporting the whole implementation and validation process, from gathering user requirements, over performing vendor assessments to writing documentation for testing and release of the tool.

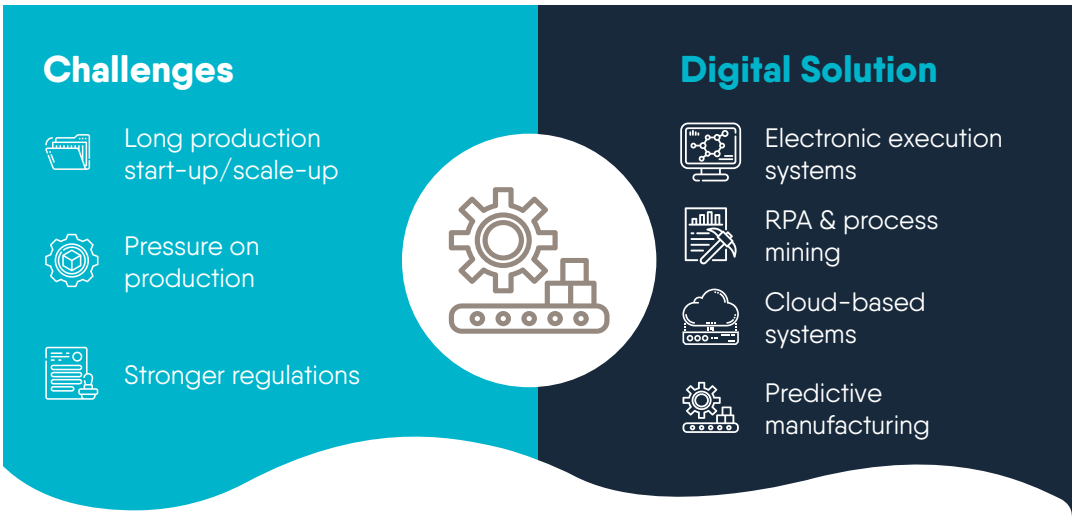
Digitalising the collection of subjects' reported outcome is performed using multiple eDiary systems that replace the paper diaries thanks to smartphone-like devices.

After receiving a vaccination during a clinical trial, subjects need to complete a questionnaire periodically. This is usually a daily record for several weeks to record the presence or absence of specific or unexpected symptoms.

The use of a digital tool increases the subjects' compliance by providing alarms and reminders to complete the diary. Additionally, data integrity and quality is also increased as subjects are provided with specific workflows for questions.

Proofing systems prevent implausible values to be entered. This also increases subject safety by sending an automated notification to the principal investigators when a subject is experiencing symptoms that require medical attention. Avertim has been hired to support the whole implementation and validation process of two new platforms and to implement a new streamlined validation approach.

Manufacturing



Digitally empowered workforce, robotization, automation and Internet of Things (IoT) driven production are some of the latest trends in digital transformation in pharmaceutical manufacturing.

Electronic execution systems

Companies have a variety of technological options to automate their laboratory activities (Laboratory Execution Systems LES) or manage the production and material flow (Manufacturing Execution Systems MES). Together with robots in the production lines and automation systems all along the process (e.g. automatic filling and packaging), it gives them more visibility and flexibility to manage their operations and supply chain. Furthermore, it helps build more consistency in the documentation from raw materials to finished products.

MES and Enterprise Resource Planning systems (ERPs) such as SAP provide tools and systems to better collect plant data, manage the quality of production processes, track orders, schedule operations, monitor performance, allocate resources, and more.

Managing increased volumes of data does not solve all issues, since companies also need to increase their knowhow and governance on how to treat the information and act accordingly. This is where advanced intelligence platforms such as **SAP HANA (S4HANA)** can help by enabling you to visualize, crunch, store and translate data from various sources into business intelligence, everywhere in the company, including outside manufacturing operations.

Cloud-based systems for quality and compliance

Digital tools are empowering employees to collaborate more efficiently across all phases of the pharmaceutical value chain. It has a special importance for quality assurance, quality management systems (QMS), and compliance activities related to manufacturing. In highly regulated Good Manufacturing Practices (GMP) environments, pharmaceutical companies have some of the highest quality requirements. In practice, this translates into a lot of data as well as complex systems, roles and responsibilities to create, review, validate and approve. Computer software providers are seizing this opportunity to propose innovative cloud-based solutions among others for eQMS, eCompliance and other smart quality and documentation systems.

Decision-makers who traditionally saw cloud solutions as non-compliant, insecure, and prone to failure or integrity issues have had their **minds changed in recent years**, due to culture and technology changes. Cloud systems can optimise security for each specific application; they also make auditing or security issue resolution faster. With cloud systems, IT departments do not need to invest themselves in high capital expenditures for infrastructure and cybersecurity.

> Digital tools are empowering employees to collaborate more efficiently across all phases of the pharmaceutical value chain.

Merck has reportedly fought over $1.3 billion in damages from the 2017 "NotPety" cyber attack which affected 30,000 computers. In such cases, cloud-based solutions can also provide a good alternative for companies willing to benefit from external digital technologies and focus their efforts elsewhere. Cloud systems also help streamline capacities to manage data access and control within and outside the organisation. Additionally, they can enable virtualisation of research. Top providers of cloud-based solutions for quality and compliance include IQVIA, Veeva Systems, Microsoft, Salesforce, Dassault Systems, Oracle, SAP.

Robotic process automation

Robotic Process Automation (RPA) has become a most-hyped technology across all industries. It refers to software-based automation services which automatically execute tasks based on given workflows and triggers.

RPA services increase efficiency by fulfilling monotonous and repetitive tasks (undertaking low-value manual work like form-filling, copy-pasting, systems-integrating, etc.). RPA also decreases the risks of human error. Use cases implementation spans across the entire life cycle of clinical systems, financial reporting, order-to-cash processes as well as across manufacturing, quality control and compliance activities.

Process mining technologies

Insight-driven companies are going even further by using ground-breaking technologies in process mining – the analytical discipline for discovering, monitoring, and improving processes. Process and task automation are best used when operations are optimised. According to Bill Gates "automation applied to an efficient operation will magnify the efficiency; automation applied to an inefficient operation will magnify the inefficiency."

Celonis is one of the fast-growing software firms offering process mining solutions. The Munich-headquartered company was born in 2011, has become a leader in its field and claims to work with five of the ten biggest pharmaceutical companies. Celonis' process mining platform offers an explorative approach and tools to find weak points in processes and optimise them in real-time. Each step of a process is precisely traced and evaluated. Additionally, the user has many options for analysis and visualization. Celonis has a stronghold in manufacturing and operations already. Furthermore, they keep expanding their intelligence systems for all business processes within organizations.

Predictive manufacturing

The increased sharing and pooling of significant amounts of generated data can lead to new opportunities in predictive manufacturing. Available analytics can help predict glitch, future trends, and help enhance operational efficiency as demonstrated successfully by Teva's production techniques for monoclonal antibodies.

The company has partnered with the German company Insilico Biotechnology to leverage bio-processing data for predictive bio-manufacturing. "By complementing our process development capabilities with Insilico's unique technology for digital bioprocess development, we can accomplish robust and efficient production of our biologics pipeline faster," says Jason Bock, Vice-President of Biologics CMC at Teva. The technology called "Digital Twins" is optimising production processes by computational simulations.

Digital factories: a case with Sanofi

Sanofi is one of the companies investing in digital manufacturing with its **factory of the future** in Framingham, USA. It uses "state-of-the-art analytical techniques that forecast and avoid variations to improve performance and ensure quality".

Sanofi described it as: "Plant operators are supported by digital collaboration, data analytics or augmented reality solutions, helping to make real-time decisions and adjustments, while simulations provide the level of manufacturing modularity and flexibility required to support personalised medicines".

The digital plants are equipped with modern sensors across all facilities and equipment. "Our employees will work alongside "Cobots" – collaborative robots that recognise their environment to operate safely and Autonomous Mobile Robots (AMR) will automatically transport raw materials, single-use equipment and finished products to different points in the facility. Advanced analytics on data from all these systems will help identify and correct potential issues on the factory floor and continuously optimise flow and orchestration of activities. Augmented reality for our technicians, paperless shop floor operations with mobile solutions and seamlessly integrated quality labs will also play key roles".

It continues, "each one of these new plants will have a 'digital twin' – a 3D computer model of the actual plant, connected directly to all the sensors and data in the physical factory.

The data flows to these digital twins giving managers a real-time view into the plant's operation. Simulation on the model provides the level of manufacturing modularity and future flexibility required to support personalised medicine".

The company details **here** how its plant in Geel, Belgium, has already implemented sensors throughout the facility monitoring more than 5,000 parameters along the production processes.

Philippe Luscan, Executive Vice President, Global Industrial Affairs at Sanofi comments: "I see great scope for using digital models and simulations to transform how we plan, design and operate our facilities from the concept through to delivering products to patients".

Avertim Reference Case

Digital in manufacturing

In one project, a team of Avertim specialists has helped deploy a paperless program aimed at digitising all paper-based activities across ten international vaccine quality control laboratories.

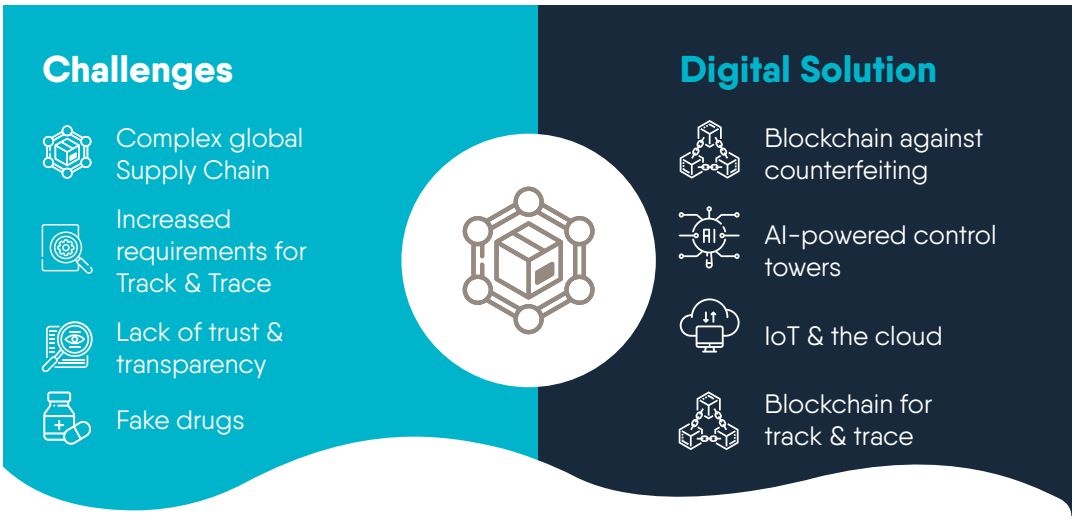
The program impacts 3,600 testing methods used by more than 1,500 QC employees. The digitisation of paper can increase the efficiency in quality control, reduce costs, reduce human errors and improve deviation handling.

While implementing such an ambitious plan, you may face some challenges, such as:

- creating a strategic alignment with top management through internal sites
- understanding scientific specifications and integrating them together with quality and compliance requirements in the system design
- liaising with various technology providers, interfacing laboratory equipment
- testing and validating computerised systems
- upgrading local IT and telecommunication infrastructure
- educating people and guiding them through the change.

Thanks to its implementation experiences, Avertim can help you become paperless too.

Supply chain



Blockchain, AI, and cloud computing are some of the technologies that are part of the digital transformation of the pharmaceutical supply chain. They help tackle problems such as counterfeiting, track and trace, and supply chain planning.

Blockchain against counterfeiting

A major issue in the pharmaceutical supply chain is counterfeiting. This creates high losses for pharmaceutical suppliers and high risks for patients. According to EU studies, the pharma industry loses on average €10 billion per year because of drug fraud. The World Health Organization (WHO) estimates that 8 percent of the medical devices in circulation today are counterfeit copies, rising above 20 percent in certain countries. In an attempt to address this issue of fraud and counterfeit goods, both the US Drug Supply Chain Security Act (DSCSA) and EU Falsified Medicine Directive (FMD) have introduced legislation that require electronic systems to trace and authenticate medication as it moves through the distribution network. Moreover, pharmaceutical companies have already intensified their efforts and investments by upgrading their serialisation techniques, using secured databases and exploring blockchain technologies. A blockchain is a continuously expandable set of data records linked to each other, similar to a journal of accounting. Each data record (or block) contains a cryptographically secure hash of its previous version. Along with time stamp and transaction data, a block can be populated with any desired data; hence it allows to trace the history of the data records irreversibly. Lastly, a blockchain makes it possible to achieve an agreement between the nodes in a decentralised network, thus creating high levels of trust in the data while simultaneously distributing it.

The FDA is currently running a pilot program named MediLedger with a consortium of 25 pharmaceutical companies. The goal of the program is to evaluate blockchain as the solution to the upcoming 2023 DSCSA requirements which calls for the tracking and authentication of returned drugs. In such a case, blockchain can be used as a single source of truth in tracking legal changes in ownership of drugs, products, and medical devices

across the whole supply chain from the manufacturer over brand owner and wholesaler to the delivery agent. The EU PharmaLedger consortium, mentioned earlier, also includes supply chain as a core use case to explore.

Blockchain for Track & Trace

SAP, being a major software provider, is very active in blockchain with regards to track and trace. It has been deploying its **"Advanced Track and Trace" application for enhanced drug authenticity** with companies such as Merck & Co., Amgen, GSK and Boehringer Ingelheim (video case with the latter). The app combines SAP technologies and its blockchain cloud platform that tracks data from IoT devices and barcode scanners "all the way from when the ingredient was produced to moving it". Predefined parameters like serial number, batch number, material information and expiration date are tracked and stored in a blockchain and can be accessed by supply chain management. It is expected that the supply chain costs will decrease when companies gain additional data on demand and purchasing behaviour. Manufacturing and shipping timelines can be reduced by using short term data and statistics to predict long-term product stability.

Another example for the usage of blockchain in pharma supply chain is a **pilot case** of BASF, who partnered with Ahrma and Qantoz to develop a reusable transportation rack equipped with Radio Frequency Identification (RFID) technology. Sensors at different points in the manufacturing process and the supply chain identify the transportation rack by its RFID chip. The information these smart IoT devices provide, for example, unique identity, purity, assay, temperature fluctuations during transportation and others are stored using blockchain technology developed by Qantoz. Proof of this concept was successfully demonstrated in 2017.

IOT and the cloud in the pharmaceutical Supply Chain

Technologies like the use of cloud computing and IoT are reaching maturity and will play an important role in the digitalisation of the pharma supply chain. As the industry's view is shifting away from singular digital improvements towards more holistic approaches, cloud solutions become the general framework in which all digital applications are set up.

Increased interconnectivity and possibility for real-time enquiries yield high cost benefits and lead to better process control. Additionally, supply chain operations become more agile and predictive. SAP or other ERP and supply chain planning tools are providing novel options helping to achieve exactly that.

"As the industry's view is shifting away from singular digital improvements towards more holistic approaches, cloud solutions become the general framework in which all digital applications are set up.

AI-powered control towers

AI and machine learning are also used to optimise the architecture of "Control Towers" (CT) in pharmaceutical supply chains. Designed upon the principles of airport control towers, they provide a digital platform with real-time data

gathering and analytics for more efficient decision making not only in logistics but also in supply chain planning tasks. These technologies can effectively manage complex tasks for humans.

At operational levels, costs can be reduced by automating transactional tasks such as making orders, entering forecasts, sending information to providers, etc. At the tactical level, AI can be used to automate decision-making in response to changing patterns, like changing product distribution; it can also create campaign or replenishment schedules.

At strategic level, AI has the biggest impact as it will support self-continuous optimisation and provide the ability to deal with unknown situations. Bots will be able to identify long term strategic trends or shifts in demand by use of leading indicators and propose fast, optimal responses. Optimisation of CT would also enable a closer collaboration with stakeholders (suppliers, transportation companies, distributors...) and enable each supply chain player to operate at their optimal level.

Avertim Reference Case

Digital in Supply Chain

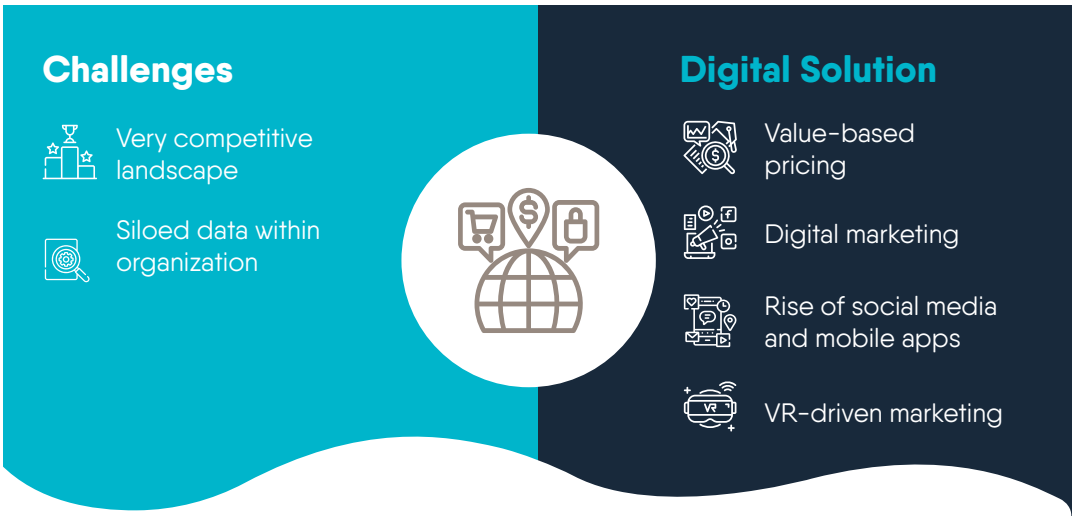
Avertim supported the specialty care unit of a major pharmaceutical company in digitalising the global quality management of their downstream supply chain.

The deviation, change control, and documentation management processes of this department were fully paper-based in the past, leading to overall slow and inefficient quality management.

By translating the client's needs into concrete user requirements, Avertim designed, built, tested, validated and deployed three separate systems. These systems were seamlessly integrated into the existing quality management operations, and all involved employees were properly trained.

Moreover, Avertim streamlined the batch release procedure for CMOs managed by the same department by creating a user-friendly dashboard. This increased the processing capabilities for acquired products into the company's portfolio.

Commercialisation



In today's evolving healthcare market, marketing and sales forces from pharmaceutical companies need to set up effective patient-centred commercial and communication approaches. Digital technologies can help achieve this.

Rise of social media and mobile apps

With internet, social media or mobile apps pharmaceutical companies have plenty of options to reach and inform patients digitally. However, they could also see exactly these digital options as a threat.

Whereas they used to be the sole gatekeepers for treatment information, discussions are now shifting towards new platforms such as healthcare websites, forums or apps.

Setting up innovative digital marketing strategies is a relatively new exercise for pharmaceutical companies. These were until now far apart from their end-users due to their historical relationships and regulations that protect patients from being influenced directly. Threats and opportunities are pushing pharmaceutical companies to enter the digital marketing conversation.

Back in 2014, Boehringer initiated its award-winning disease-focused "ChatAFib" tweet chat sessions on Twitter, giving patients and health care professionals the opportunity to chat about stroke and atrial fibrillation non-treatment related topics.

VR-driven marketing

Augmented and virtual reality technologies can also become innovative digital tools to help inform patients. Some companies such as GSK have already piloted such immersive tactics. The British company launched its Excedryn brand together with **a VR-driven campaign called "The Migraine Experience".** Patients could set their individual symptoms in a VR device and hand it over to their friends and family members so that they could experience what a migraine attack feels like. The campaign generated many new engagements as well as sales boosts.

Digital marketing

Other opportunities that can be offered to companies are devices and medical apps to get direct digital input from their patients. From a commercial point of view, this allows companies to deploy advanced analytics solutions to better understand patient profiles and behaviours, subsequently adapting their prescription strategies as well as their targeting of providers. Pharmaceutical companies can learn more about care providers for patients affected by a specific disease. As a result, they can better focus on building the relationship toward those providers. Here, digital tools can help mine electronic medical records to get these insights. **Lyfegen** is one in the growing number of start-ups and tech providers pioneering in data-driven healthcare for high-cost therapies. The Swiss-based company offers a digital platform to share necessary data-points for any value and data-driven agreements securely.

Value-based pricing

Reimbursement schemes based on results, or so-called "value-based pricing", receive **growing interest from European countries** and around the world, especially in the growth of personalised medicine.

Here, digital tools offer the possibility to get more data from patients, drug payments, insurance claims, apps and clinics. Harvesting real-world data will enable to provide evidence of drug efficacy by measuring health outcomes relative to monetised inputs.

This triggers pharmaceutical companies to get ahead of the curve on real-world evidence and adopt new value-based commercial and pricing strategies in a completely new cost and risk paradigm.

In a recent case, health insurers Cigna Corp. and Aetna Inc., said they will pay Novartis for its newly approved heart failure medication based on how well the drug does its job. The latter will be evaluated by the reduction in the number of patients hospitalised due to heart failure.

Avertim Reference Case

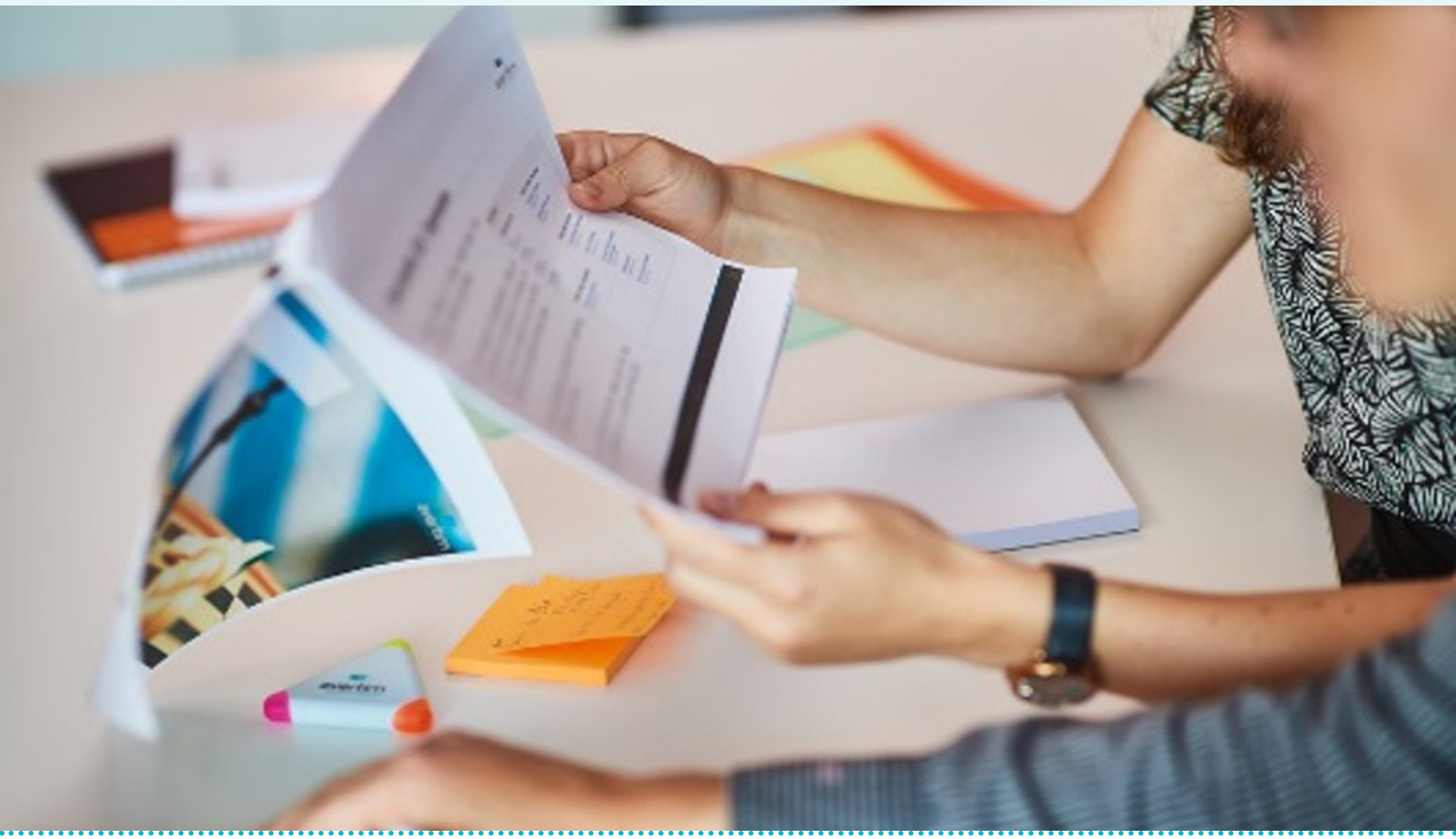
Digital in commercialisation

In 2019, a leader in the diagnostics industry mandated Avertim to help establish a 3-year digital marketing strategy plan. The basic observation was simple, yet eloquent: the diagnostics industry is taking a great digital turn with new big tech players and start-ups entering the market and gaining market shares. The client was looking for support to keep up with this innovative pace in terms of digital marketing and ways to engage with clients and patients.

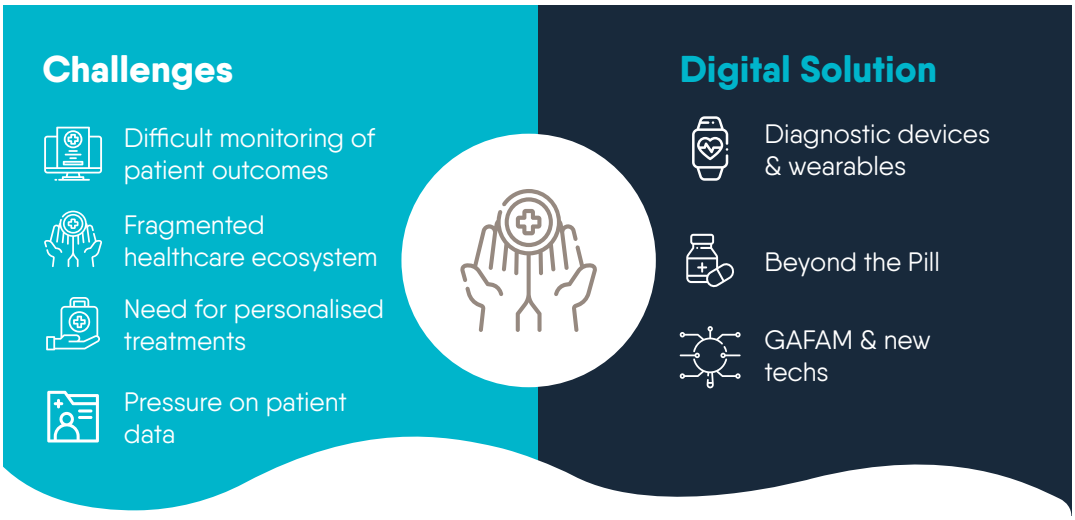
Avertim conducted a benchmark study on state-of-the-art in digital marketing with cases from the life sciences and medtech industry as well as other industries. Workshops have been organised with the marketing department and transversal stakeholders to address the strategic question: what should be done to make the switch to digital and how would we ensure our client's market leader position during this change?

Participants were invited to different workshops:

- to better define features needed by users, ways to better get field feedback and "voice of the customer"
- set up actions plan accordingly, rank possible paths based on specific criteria and measurable indicators as well as organise it in a drafted roadmap.



Healthcare

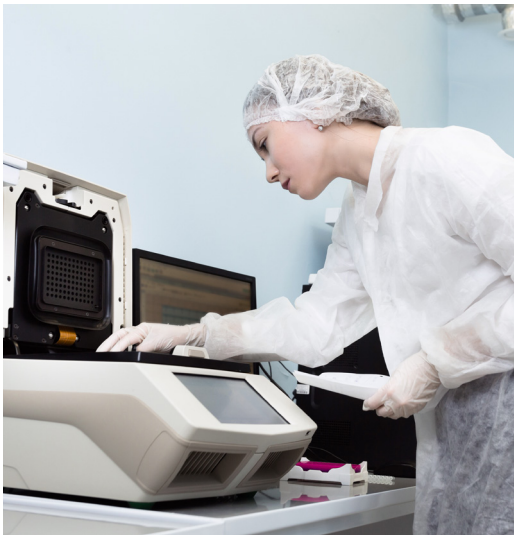


Progress in technology, connected devices, intelligent tools and connected ecosystems are helping create a patient-centric healthcare system. Health gadgets are emerging fast as serious therapeutic options. Patient care becomes smart, occurs at anytime, anywhere, in a customised and empowered way. This creates opportunities for pharmaceutical companies to better leverage treatment data, personalise drugs and patient journeys.

Diagnostic devices and wearables

Digital tools, connected health devices and other diagnostic gadgets are spreading through our homes and our healthcare journeys. After equipping our cars with sensors and our homes with smart applications, we see that our health is also becoming data-driven and monitored in real-time.

In recent years, patient data collection has been facilitated by wearable activity trackers, such as Fitbit, Garmin, and a host of other brands. They have even



been used successfully to measure step counts, activity intensity, heart rate, and sleep-related endpoints in clinical trials that span multiple areas of medicine such as oncology, cardiovascular disease, diabetes, rehabilitation, mental health, etc. This shows that the development of wearables offers the opportunity to collect key patient's health parameters.

In a recent study, researchers from the Scripps Research Translational Institute find **COVID-19 signals in daily activity data from Fitbits** and smartwatches. Such findings can contribute to help quickly identify, trace and isolate

infected individuals with real-time data points. The data model in the study used patient sleep time, movements, or deviations from daily patterns. It rightly predicted positive results in 80% of the cases. Although such technology application needs further testing and proof of effectiveness, it sparks a lot of attention justifying to further improve the algorithm. Fitbit received an award close to $2.5 million from the US Army's medical research team to potentially try the concept for military personnel.

In an older example from 2017, **Roche bought the former diabetes management start-up** MySugr. MySugr compiles data from Roche's blood glucose meters, fitness trackers and other smart devices in one convenient application. The application is already being backed by insurance companies, including Allianz, Barmenia, UKV and Gothaer. Besides, it offers great potential for another trend in healthcare: gamification to increase self-care.

Other applications include the use of smart refrigerators or smart fitness devices for the collection of nutritional information. This can allow real-time monitoring and alerts to be sent to caregivers when there is a need for intervention.

What about regulations for these smart devices? Even though regulation oftentimes constrains innovation, the FDA has expanded the use of wearable technology for patient reporting as part of clinical trial design and provided clearer guidelines for the use of risk-based monitoring.

In the event of the COVID-19 pandemic, the FDA has **released a list** of remote or wearable patient monitoring devices authorised for use during the COVID-19 public health emergency.

It includes patient monitoring devices such as: "non-invasive remote monitoring devices that measure or detect common physiological parameters" and "non-invasive monitoring devices that wirelessly transmit patient information

to their health care provider or other monitoring entity". (FDA)

Another promising approach that also uses wearables to track progress is the combination of gamification and employer incentives like **Healthcoin.** With Healthcoins the employee can set milestones and daily goals, and the employers can reward employees for healthy behaviours.

The rise of companion diagnostics

Another area where digital and diagnostic technologies play an important role in improving patient health outcomes is the development of companion diagnostics (CDx) and complementary diagnostics by pharmaceutical companies. These technologies are usually in-vitro diagnostic (IVD) devices, test kits or imaging tools. They provide essential information on the safe and effective use of a drug or biological product or aid the risk-benefit assessment about the use of the therapeutic product. The adoption of such devices is crucial, especially with the rise of chronic diseases, value-based treatments and personalised medicine.

For instance, CDx assays have been developed for breast cancer treatments after discovering that women who have an over-expression of certain receptor proteins have a clinically meaningful response to a given monoclonal antibody. As another example, Roche **recently announced** FDA approval of FoundationOne Liquid CDx, a qualitative next-generation sequencing-based IVD test that analyses more than 300 cancer-related genes and multiple genomic signatures to help inform treatment decisions for all solid tumour cancers using a simple blood draw.

CDx have become more relevant and effective due to technical and bioanalytical progress like the discovery of predictive and prognostic biomarkers as explained in a paper published in 2017 by the Clinical and Translational Science Journal. These are used to identify individuals who are more likely to experience certain health outcomes from exposure to a medical product.

According to a **recent study**, the global CDx market is expected to reach a valuation above 8 billion dollars by 2027 with a phenomenal CAGR of 20.3% over the forecast period. Major indication areas for the use of CDx are cancer, cardiovascular diseases, neurological diseases, and infectious diseases.

Beyond the Pill programs

With all the digital options available and the rise of value-based healthcare, pharmaceutical companies have new ways to answer healthcare issues and previously unmet patient needs. This is particularly true in chronic diseases where patient healthcare systems sometimes fail at maintaining effective chronic care.

Many companies are launching “Beyond the Pill” programs to structure their plans by offering additional services to their products. They aim at improving the patient experience and health outcomes as well as gaining strategic competitive advantages. This occurs in the whole life cycle but is most relevant in the health care stage.

Pharmaceutical companies are free to launch their own tools or partner with health care providers, clinics and pharmacies to offer additional

resources to patients. This might be in the form of websites, forums or social media feeds. These tools can ultimately help patients in various ways: receiving original diagnosis information, expressing preferences in treatments, getting incentives for their adherence to medication, securing financial assistance or connecting with other patients and community experts.

Bayer is one of the companies that have created an integrated strategy to help multiple sclerosis (MS) patients in their daily life under Betaseron treatment. The company has developed a whole range of value-adding services through its MS Gateway under the banner "**Betaplus**". Patients get access to a "BETA Nurse"; a network of trained nurses available for visits or online consultations. They can ask all their questions about the treatment, the injection training or potential side effects. This service offers valuable information for patients, but also saves time for practitioners and health care professionals (HCPs). Patients can also use the smartphone application "myBETapp" to schedule and record their injections. The app also tries to improve patients' feelings of wellbeing or motivation through a "Wellness Corner" with online exercises and online games.

The rise of GAFAMs in the healthcare game

While attending conferences on pharma trends, one easily notices a certain trend: the discrete, but obviously growing competition of big tech players such as Google, Apple, Facebook, Amazon and Microsoft in the data-driven healthcare market is a clear concern from the traditional players in the pharmaceutical industry. Should these companies fight back? Create their own platform? Be against collaboration and risk missing out?

One thing is certain; change is already happening with examples such as Project Nightingale from Google Cloud and Acenscion CareKit from Apple, Preventive Health from Facebook and Microsoft cloud for healthcare. The potential control over health data from the "cloud cartel" is creating a lot of discussions and controversies. It has been the case in 2020 in France when the government allowed the storage of health information from the Health Data Hub, the French platform for centralising population health data, managed by Microsoft. Moreover, it also shows that the healthcare industry will have to include all players in the game, especially those bringing a pure data-driven perspective.

So does Google's Verily already cooperate with Novartis, Otsuka, Pfizer and Sanofi to run clinical trials in indications such as cancer, diabetes and mental health, as reported in this **article**. It states that Verily aims "to collect a 'deep dataset' from each participant through clinical visits and interactive surveys and polls, and use that data to establish what it means to be healthy and how health transitions to disease."

Cooperation between big pharma and start-ups

Similarly, pharmaceutical companies will need to learn how to best cooperate with start-ups to leverage the digital revolution. Healthcare start-ups are more agile when it comes to exploring new technologies and are much closer to customers.

One example of collaboration between pharmaceutical companies and start-ups is the **Accelerator program of the German Merck**. The company has numerous programs for innovation and cooperation with start-ups including workshops, demos and hackathons. Every year Merck selects up to twelve start-ups to work together with their employees on pilot projects and proof-of-concept studies, creating a win-win situation for both parties. The UK-based start-up CCG.ai is one of the companies that collaborate with Merck in the 2020 Accelerator program. The accelerator presents their activity: "CCG.ai has built the software to enable data-driven precision oncology and systematically develop biomarkers of treatment response. By uniting the power of AI with increasing amounts of clinical and genomic data, the company has created the potential to transform cancer treatment and enable oncologists to make smarter decisions on treatment choice."

Avertim Reference Case

Digital in healthcare

Rare disease manufacturers providing patient treatments for neurology disorders have a hard time monitoring the conditions of their patients, as is the case, for example, with epilepsy or Parkinson's diseases. Thanks to the applications of artificial intelligence, companion diagnostics and other connected devices empower patients and improve health outcomes. This is what Avertim has helped achieve in a tech scouting project with a leading pharmaceutical company.

Our team helped collect 500+ tech solutions from around the world, analyse and rank them according to tailor-made criteria such as patient value ("desirability"), technology ("feasibility"), and business ("viability"). Additionally, we implemented a dedicated knowledge tool to help move the solutions through the innovation funnel and share competitive intelligence throughout the entire company.

4

How

How can leaders in the pharmaceutical industry approach a digital change within their company? As presented previously, various options are being made available and piloted in multiple departments within pharmaceutical companies. How can a company monitor these options, prioritise them, make decisions for technological choices and investments, and drive the change internally?

Ensure strategic alignment

As a prerequisite for a successful journey, decision-makers will need to make sure the roadmap and portfolio of digital initiatives are aligned with the company or unit strategy, whether it is to focus on cost and performance improvements, or direct benefits in terms of patient health outcomes.

Increase corporate agility

In parallel, organisations would like/feel a need to increase their agility to ensure they pilot and execute new digital solutions faster.

A great opportunity to do so could be to use the COVID-19 crisis learnings to understand how the organisation can adapt its plans faster and act digitally. You can also learn more **here** about Avertim and our Corporate agility framework – our methodology and Agile philosophy aiming at executing the tasks faster making it easier for organizations to adapt to change.

Focus on management buy-in

Since the top management's buy-in remains essential, fostering digital innovations from the bottom up has been observed by our teams as a key success factor from recent implementations of digital programs. Avertim has helped global pharmaceutical companies set up new programs for digital transformation within their operations, from R&D to manufacturing and quality.

Create solution-oriented knowledge platforms

In a recent case, we worked with a global pharmaceutical manufacturer to set up a new "Digital & Data Analytics" taskforce, in order to bring more digital innovation to their operations. Our team developed an inventory of digital and innovative solutions called the "Digital Solutions Store".

The Store has four objectives:

1. provide internal visibility on solutions and ongoing deployments
2. help international sites find the right solution answering their pain points
3. help global teams prioritise based on local needs
4. create alignment with relevant stakeholders for each solution

The digital and innovative solutions were clustered in several levels of digitalisation such as "paperless" (paper to eSolution) or "IoT" (data-driven

operations). They can be classified as "simple solution", "in development" or "in live" stage. In one year, 100 solutions were recorded into the Store. Moreover, each solution is described in detail within a one-pager, giving information on its objectives, technological components and deployment insights based on first-hand internal experiences. Dedicated deployment planning is also documented and made available to all colleagues.

Use bottom-up approaches and mobilise your internal communities

A bottom-up approach was chosen to bring multiple sites to use the Digital Solutions Store as a reference platform which has brought optimal value to ease the required digital and cultural change effort. In this approach, local teams became the central piece for information collection and sharing within the organisation. Digital points of contact are identified and mobilised as ambassadors. They join monthly digital sharing sessions and other online events to share knowledge and experience, avoiding unshared isolated initiatives. During each session, they pitch three local solutions and share their experience. They then frequently organise local meetings with the site leadership to report insights from the community and assess potential for local adoption. Capabilities to develop such active digital communities and share knowledge have become a key factor for a successful transformation.

At the global level, the top management buy-in was confirmed and proved to be essential to steer efforts across the entire company. Specific board meetings were set up with global management and representatives from sites, strategy, automation, IT, data analytics and QA, in order to align, prioritise and support solution implementation.

Define relevant criteria for prioritisation

Digital options often come as a trade-off between business, technology, and management priorities. Advanced solutions may seem revolutionary but not technically feasible yet. Other solutions may create great value for patients but may not integrate well in the company's business model and product offering.

Do you want to learn more about how Avertim can help?

Get in touch with us **here**.

"Digital transformation requires to change organizational processes and mindset to allow better transversal communication and agility across internal organizational silos. Finding the right balance between business expectations and technical possibilities is mandatory to successfully drive this change. This is where Avertim can help.

Matthieu Deruel, Senior Business Manager

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