An Overview on Top 10 Pharma Industry Trends & Innovations 2022

Dr. G. Dharmamoorthy[1]*, Dr. M. Sabareesh[2], Dr. Anna Balaji[3], Dr. P. Dharaniprasad[4], T. Swetha[5],

P.Vineeth Bharadwaj[6],R.Sudharshan Adhithya[7], P.C Harish reddy[8]

Department of Pharmaceutical Analysis, Sree Vidyanikethan college of pharmacy

Sree Sainath Nagar.Rangampeta, Tirupathi-517102 Chittoor (dt).

CORRESPONDING AUTHOR

Dr.G.DHARMAMOORTHY

Associate professor &HOD

Sree Vidyanikethan college of pharmacy, Sree Sainath Nagar.Rangampeta

Tirupathi-517102 Chittoor (dt).

Mobile no; +91 9603774847

Email id dharmamoorthy111@gmail.com

Reviewers

1) **Dr.V.SHANMUGAM**

Professor & HOD, Dept. of Pharmaceutics, Sree Vidyanikethan college of pharmacy

Sree Sainath Nagar. Rangampeta, Tirupathi-517102, Chittoor (dt).

Mobile no; +91 9052155880

Email id;shanmugam.v@vidyanikethan@edu

2) **Dr.R.JAYARAMAN**

Professor & HOD

Dept.of Pharmacology, Sree Vidyanikethan college of pharmacy

Sree Sainath Nagar.Rangampeta Tirupathi-517102

Mobile no .9677660403

Email id jayaraman.r@vidyanikethan.edu

Abstract

For more than a decade, analysts of the pharmaceutical industry have argued that the conventional blockbuster model of drug discovery and development is unsustainable, despite many years of investment in new life science technologies. Explanations have included a failure of innovation capacity and low productivity, a focus on incremental rather than radical innovation, excessive regulatory barriers and a lack of venture capital investment. However, an alternative argument can be posed that the pharmaceutical innovation model has been remarkably resilient and multinational companies have been extremely robust in maintaining their market dominance. Pfizer's recent announcement that it will close a major R&D site at Sandwich (Kent, UK) is a clear blow both to the North Kent regional economy and to the broader UK research base. Nevertheless, it illustrates a broader global trend in Big Pharma where large-scale merger and acquisition activity is followed by major company restructuring and R&D rationalisations as firms try to implement strategies to meet the growing demands of blockbuster innovation and sustain revenue streams. In this article, we consider the sustainability of current pharmaceutical innovation strategies in the context of the challenges and opportunities posed by the life sciences. We argue that the regulatory system plays a predominant role in shaping innovation trajectories. We also consider the benefits of 'smart regulation' and conclude with some comments about the future of the big pharma sector. Our key question is whether the pharmaceutical R&D model is sustainable and, if not, what alternatives are available.

Keywords: Innovation, Pharma Industry, startups,trends etc.

Introduction

The pharmaceutical industry is witnessing a massive revamp. Traditionally slow in the adoption of technology, the industry is now undergoing rapid changes due to the development of several technologies. The prominent pharma industry trends include artificial intelligence (AI), additive manufacturing, blockchain, and other Industry 4.0 technologies. The increasing investments, growth of technology startups, and the expiry of several key patents, as well as increasing inter-organizational collaborations and a favourable regulatory environment, are spurring innovation across the pharma industry trends.[1]

Innovation Map outlines the Top 10 Pharma Industry Trends & 20 Promising Startups

For this in-depth research on the Top Pharma Industry Trends & Startups, we analyzed a sample of 1745 global startups and scaleups. The result of this research is data-driven innovation intelligence that improves strategic decision-making by giving you an overview of emerging technologies & startups in the pharma industry. These insights are derived by working with our Big Data & Artificial Intelligence-powered StartUs Insights Discovery Platform, covering 2 500 000+ startups & scaleups globally. The platform quickly delivers an exhaustive overview of emerging technologies within a specific field as well as identifies relevant startups & scaleups early on.

In the Innovation Map below, you get an overview of the Top 10 Industry Trends & Innovations that impact pharma companies worldwide. Moreover, the Pharma Innovation Map reveals 20 hand-picked startups, all working on emerging technologies that advance their field. To explore custom insights, get in touch.[2,3]

Top 10 Pharma Industry Trends

1. **Artificial Intelligence**
2. **Big Data & Analytics**
3. **Flexible Production**
4. **Precision Medicine**
5. **Additive Manufacturing**
6. **Blockchain**
7. **Extended Reality**
8. **Real World Data**
9. **Digital Therapeutics**
10. **Curative Therapies**

Tree Map reveals the Impact of the Top 10 Pharma Industry Trends

The Tree Map below illustrates the top 10 pharma industry trends that will impact companies in 2022. From drug discovery and development to medical imaging and patient engagement, artificial intelligence occupies a prominent position in the industry. Along with big data and analytics, more than a third of pharma startups are working on software solutions for the industry. There is still a lack of access to basic medicines in many regions of the world, prompting demand for flexible pharmaceutical manufacturing. The use of real-world data to collect accurate patient experiences, blockchain to securely transact and manage patient records, and augmented, virtual, and mixed reality (AR, VR & MR) solutions also find a place in the top 10 pharma industry trends. However, these trends cover only a small fraction of the breadth of innovation in the industry. Based on your specific criteria, your top trends can look quite different.

Global Startup Heat Map covers 1745 Pharma Startups & Scaleups

The Global Startup Heat Map below highlights the global distribution of the 1 745 exemplary startups & scaleups that we analyzed for this research. Created through the StartUs Insights Discovery Platform, the Heat Map reveals that the United States is home to most of these companies while we also observe increased activity in India as well as Europe, particularly in the UK and France.

Below, you get to meet 20 out of these 1 700+ promising startups & scaleups as well as the solutions they develop. These 20 startups were hand-picked based on criteria such as founding year, location, funding raised, and more. Depending on your specific needs, your top picks might look entirely different.[5]

Top 10 Pharma Trends in 2022

1. Artificial Intelligence

The use of artificial intelligence (AI) is accelerating drug discovery and development processes. Startups are exploring the use of these technologies to address the various challenges in the pharma industry, such as automation and optimization of the manufacturing processes, as well as designing effective marketing and post-launch strategies. Patient identification is a crucial step in the drug discovery and development process, especially for

conducting clinical trials. AI simplifies the identification of eligibility criteria and the inclusion of patients and also makes the cohort identification process faster and cheaper.

Pangaea Data – Patient Cohort Identification

Pangaea Data is a British startup that uses unsupervised AI algorithms to identify patient cohorts for drug discovery, clinical trials, and real-world evidence (RWE) studies. The machine learning-based software scans through electronic health records (EHR) and unstructured doctors' notes to find the right patients based on phenotypes. The startup also develops a library of AI models for different disease areas.

InVivo AI – Drug Discovery

Canadian startup Invivo AI develops novel algorithms for drug discovery. The startup uses different machine learning approaches, such as few-shot learning, reinforcement learning, active learning, and representation learning, to aid the drug discovery process. The deep learning solution uses small and noisy datasets to predict and optimize potential drug candidates, further eliminating the need for large datasets.

2. Big Data & Analytics

The pharma industry requires high-performance systems to analyze the large volumes of data generated during the drug discovery and development process. Pharmaceutical companies use third parties to share data with collaborators, making data management a crucial area of focus. The advancement in analytical techniques is also turning historical and real-time data available with pharmaceutical companies into valuable assets for predictive, diagnostic, prescriptive, and descriptive analytics. Moreover, these analytics techniques are used on almost all types of medical data from patient records, medical imaging, and hospital data, to name a few.

Pryml – Secure Data Collaboration

Belgian startup Pryml develops a platform that allows data scientists to build applications on confidential or sensitive data of organizations. Pryml creates a synthetic version of the confidential data available to pharmaceutical companies. This enables the restricted sharing of this data with third-party companies for business applications or research collaborations. Pryml's solutions integrate within the customers' data architecture for the development of solutions such as predictive models for drug recommendations.

Pomicell – In-Silico Modeling

Israeli startup Pomicell offers software tools for big data analytics in pharmaceutical research and development (R&D). The startup utilizes machine learning techniques to analyze and aid in the development of in-silico models. The startup further builds customized drug development road-maps by augmenting the available data, analysis, and insights through matching and in-silico modelling.

3. Flexible Production

The pharma industry is exploring new ways of manufacturing due to the changing market dynamics, such as small batches for precision medicine. Single-use bioreactors are also gaining popularity as they reduce downtime and increase productivity. These bioreactors achieve this by eliminating complex steps like cleaning and validation between separate production stages. New types of bioreactor systems and continuous manufacturing processes address the increasing focus on biopharmaceuticals. In addition to eliminating downtime, continuous manufacturing has low energy needs, achieves high productivity, and minimizes the amount of waste.

Cellexus – Single-Use Bioreactor

Cellexus is a Scottish startup that makes single-use airlift bioreactor systems. The startup's patented airlift technology uses bubbles instead of mechanical mixing to move cells and nutrients. The reactor comes with disposable bioreactor bags, and an integrated heater, and offers precise regulation of biochemical parameters such as pH, dissolved oxygen, and temperature. The single-use system can be used for a variety of cell cultures and fermentation and the startups have achieved growth of bacteria, yeast, microalgae, and bacteriophage amplification.

Secoya Technologies – Continuous Manufacturing Optimisation

Belgian startup Secoya Technologies offers novel technologies for production processes by tailoring the continuous manufacturing process equipment down to the ideal scale. Microstructured elements such as microfluidic droplet generators are used for optimizing manufacturing processes. The startup's solutions find use in intensified chemical synthesis, crystallization, pervaporation, and micro-encapsulation.

4. Precision Medicine

Precision medicine comes from the idea of treating each patient as a unique individual. Advancements in omic and data analysis are providing new insights into how the human body responds to drugs. This knowledge, along with advanced manufacturing methods such as additive manufacturing, is making personalized medicine a reality. Drug exposure models determine the pharmacokinetic and pharmacodynamic properties of drugs for arriving at the right dosage for drugs based on age, sex, comorbidities, and other clinical parameters.

ExactCure – Drug Exposure Model

ExactCure, a French startup, offers a software solution for simulating the effects of drugs on a patient's body based on personal characteristics. The startup makes use of population pharmacokinetics, as well as scientific literature data, for real-time prediction of efficacy and drug interaction, on each individual. ExactCure is developing drug-specific exposure models for drugs under investigation for the treatment of COVID-19.

Tepthera – Individualized Cancer Vaccine

Swiss startup Tepthera offers platform technologies for the identification of T-cell antigens. The *MEDi* platform helps in the rapid identification of tumour-specific antigens from patient

human leukocyte antigens. After the selection of antigens, the solution identifies tumour-specific epitopes and then monitors antigen-specific T cells. The platform provides patients with individualized therapeutic vaccines for treating their conditions.

5. Additive Manufacturing

The need for precision medicine is also making pharmaceutical companies rethink the manufacturing process. A lot of research is underway for making advanced 3D printers that print tissues or cells. 3D printing of human tissues has great applications in drug development, organ engineering, and regenerative medicine. This allows the development of age or physiology-dependent medical formulations, as well as precision pills. Bioprinters also help in pushing innovation in bio inks, tissue engineering, and microfluidics.

FabRx – Printed Pill

FabRx is a British startup that manufactures *M3DIMAKER*, a 3D printer for making personalized pills. *M3DIMAKER* uses proprietary technology for direct powder extrusion. The single-step printing process uses a single screw extruder for the extrusion of powdered material. It manufactures pills with properties such as sustained or delayed doses, and multidrug combination pills (polypills). The printer also enables small batch production for clinical trials and precise personalized dosage forms for individuals.

Frontier Bio – Tissue Bioprinter

The US-based startup Frontier Bio offers *FLUX-1*, a 3D bioprinter for making human tissues. The startup prints tissues as an effective way to test new pharmaceuticals. Frontier Bio addresses the limitations in making tissues have desirable structures and features with a good cell survival rate. *FLUX-1* employs the electro-hydrodynamic printing (EHDP) technique to deliver tissues with micro and nano-scale features, as well as higher cell survival rates.

6. Blockchain

Blockchain technology is very significant for the pharmaceutical industry in every stage of the production and distribution of drugs. The stakeholders in the pharma industry are, in general, extremely secretive about their data due to the sensitive nature of the data. Blockchain technology is also being explored to tackle the use of counterfeit medicines and substandard drugs that enter into the pharmaceutical supply chain and kill thousands of patients every year. The digitalization of transactions makes blockchain a promising solution for tracking and securing the pharma transaction ecosystem.

PharmaTrace – Smart Contracts

PharmaTrace, a German startup offers a blockchain-based ecosystem to secure data and deploy smart contracts in the pharmaceutical industry. The ecosystem provides a secure system for sharing crucial and sensitive information between stakeholders in the pharmaceutical marketplace. PharmaTrace uses smart contracts implemented in *Hyperledger Fabric* to address this trust deficit. Moreover, the network provides precise control and security over the information being shared.

Veratrak – Pharma Supply Chain

Veratrak is a British startup offering a blockchain-based document collaboration and workflow management platform for the pharmaceutical supply chain. The platform enables secure document sharing across supply chain partners with immutable audit logs. Good automated manufacturing practice 5 (GAMP 5)-compliant cloud-based software further lets stakeholders, within and outside organizations, collaborate at various stages of the pharma supply chain.

7. Extended Reality (XR)

Mixed reality (MR), virtual reality (VR), and augmented reality (AR) is enabling visualizations like never before. Pharma startups are exploring the possibilities of extended reality technologies in pharmaceutical research and manufacturing spheres. Extended reality tools enable data-rich and meaningful real-time location-agonistic interaction among research teams. Startups are making human augmentation in pharma a reality through extended reality wearables and tools.

Name – VR Collaboration Tool

Name, a US-based startup, offers VR collaboration tools for atomic, molecular, and protein visualization. The VR-based molecular visualization tool by Nanome imports molecular data from public databases or custom inputs. It lets researchers design proteins, iterate 3D structures, and also work in a virtual workspace with global team members.

Goodly Innovations – AR Suite

German startup Goodly Innovations develops *OptiworX*, an AR suite for pharma and biopharma manufacturing. The solution enables technicians and line operators to increase their productivity and efficiency by prompting various tasks in real-time, in an AR environment. The startup's modular design allows for both standalone and connected systems, enabling two-way data flow. Additionally, this suite supports all shop floor processes like manufacturing, filling, primary packaging, and secondary packaging.

8. Real-World Data

Real-world data (RWD) and real-world evidence (RWE) are transforming innovations in the pharmaceutical industry. RWD includes patient health status, treatment data, and health reports collected routinely. The pharmaceutical industry, owing to its research-intensive nature, has to make sure that the data they use is reliable and of real value. The availability of real-world data enabled by the Internet of Things (IoT), sensors, and wearables is restructuring the way the pharma industry is functioning.

Graticule – Unstructured Patient Data

The US-based startup Graticule creates structured data sets from unstructured RWD sources. The startup offers data subscriptions and on-demand data collaborations to pharma clients for uncovering value in RWD. Graticule makes use of clinical notes, free text, and images, as well as non-clinical data for data completeness.

OncoChain – Oncological Data

Romanian startup OncoChain offers a research platform based on a de-identified real-world oncological patient database. The startup's solution enables early detection and timely intervention for cancer detection, treatment, and cure. The *OncoChain Analytics* tool also provides real-world evidence insights for regulatory decision-making, clinical trial design, and multi-centre studies.

9. Digital Therapeutics

Digital therapeutics deliver evidence-based therapeutic interventions using software to prevent, manage, or treat physical, mental, and behavioural conditions. These non-pharmacological, tech-driven solutions are either stand-alone or used along with medications, devices, or therapies. Digital therapeutics let each individual have greater control over their health and outcomes.

Cognitive – Neuro-Rehabilitation

Cognitive, a US-based startup, offers evidence-based digital therapeutics for the treatment of neurocognitive and neuromotor impairments. Its neurorehabilitation treatment uses a medical device to help patients recover from a stroke. *cognitive*, the startup's VR headset, further immerses individuals in a virtual resort world. Consequently, the brain develops new brain circuits, helping in the recovery of brain-body control. With the help of proprietary algorithms, the solution modifies the challenges for patients based on improvements in their cognitive functioning.

Dopavision – Eye Treatment

German startup Dopavision is making a smartphone-based digital therapeutic for myopia. The startup's solution aims to slow down the progression of myopia in the young population, especially children. The solution achieves the activation of dopamine, a neurotransmitter that plays an important role in eye growth regulation. Dopavision is currently undertaking pre-clinical trials of the digital therapeutic.

10. Curative Therapies

There is a paradigm shift happening in the area of treating illnesses from managing diseases to curing diseases altogether. Curative therapies such as cell and gene therapies are changing the way we deal with chronic diseases or difficult-to-treat conditions by eliminating the need for long-term treatments. In gene therapy, genetic material is introduced into the cells to compensate for abnormal genes or to make a beneficial protein. Genetically engineered viruses are the most common vectors used for gene therapy.

Mogrify – Cell Therapy

Mogrify is a British startup that develops a proprietary direct cellular conversion platform to transmogrify any mature human cells. The platform technology identifies the transcription factors or small molecules required to convert any mature cell into any other mature cell type by analyzing sequencing data and regulatory networks. Mogrify develops novel cell therapies

for musculoskeletal, auto-immune, and cancer immunotherapy, as well as ocular and respiratory diseases.

Lacerta Therapeutics – Gene Therapy

The US-based Lacerta Therapeutics is a clinical-stage gene therapy startup working on cures for the central nervous system and lysosomal storage diseases. The startup's proprietary adeno-associated virus (AAV) vector technology platform develops novel AAV vectors with improved transduction, tissue- or cell subtype-selectivity, and immune escape profiles. Lacerta further offers novel capsid variants and a scalable vector manufacturing platform with limited production components.

Recent business dynamics show that innovations continue to drive the pharma industry in 2022. With the traditionally slow adoption of the technology industry, pharma is under rapid evolution for innovations. The increasing investment, growing technology startups, amplifying inter-organizational collaborations, and favourable environment are spurring innovations across the pharma trends.

One of the leading pharmaceutical companies in 2022, Johnson & Johnson reported sales of $23.3bn in the third quarter of 2021 indicating a rise of 10.7% compared to the same quarter in 2020.

As global pharmaceutical manufacturing market has crossed $400 billion. Reading the numbers, the US and European markets are estimated to be worth $635 bn and $315 bn in sales, respectively, by the end of 2024. Yet, how will the industry move forward to 2024 in 2022?

The pharma industry focuses on the ability to meet rising client expectations by leveraging AL and ML. A detailed emphasis is being made on pharmacovigilance, blockchain, RWD, and improved cybersecurity. Nonetheless, 2022 calls for the pharma industry to move ahead and pay attention to pharmaceutical trends to shape up the global market for the year.[7,8]

Here are the top 10 trends in pharmaceutical industry innovations to embrace in 2022.

1. Rise in Pharmacovigilance Market

Vaccines and medicines may have unexpected and undesirable side effects calling for extra emphasis on calculating drugs' quality and their usage. This is where "Pharmacovigilance" is derived from the Greek word, Pharmakon which means a medicinal substance, and the Latin word, Vigilia which means to keep a watch.

Pharmacovigilance signifies a set of scientific activities for drug effects prevention and other medicine-related problems. The ultimate goal stands to optimize the benefit-risk ratio of healthcare product usage by sharing validated information with patients and HCPs.

Developing effective and safe medicine with secure preclinical and clinical software requires a huge amount of high-quality datasets. This helps in making it possible to implicate data mining for critical decision-making along with risk assessment.

2. Artificial Intelligence & High tech

The use of AI has accelerated drug discovery and developmental processes. Various **AI startups** are aiming to explore the use of technologies to address the various challenges associated with the pharma industry.

It implies the inclusion of automation and optimization of manufacturing processes and strategizing effective marketing and post-launch strategies. The most prominent step in the drug discovery and development process is “Patient Identification”.
Artificial Intelligence (AI) helps identify the eligibility criteria and inclusion of patients. Further, it also makes the identification process easy, quick, and economical.

3. Big Data and Analytics

The Pharma industry demands high-performance systems for analyzing large volume data to render during the drug discovery and development process. In general, pharma companies use 3rd parties to share data with collaborators to make data management an area of focus.
The advancing technology aims to turn historical and real-time data and analytics of pharmaceutical companies into valuable assets.
They help in diagnostic, predictive, and descriptive analytics. Additionally, these analytics are leveraged for all kinds of medical data acquired from patient records, hospital data, and imaging centres, to name a few.

4. New & Agile Operating Models

The increasing volume of remote network distribution has driven organizations to re-evaluate network costs and operating models. It is likely to bring talent distribution and make manufacturing more flexible.
These newly developed models also demonstrate newly emerging trends to enable the program, to operate and interpret data simultaneously keeping up with technological advancement.
Numbers say that more than 80% of US pharma executives are inclined towards agile working methods. These also indicate that organizations will experience a simple structure to avoid the traditional sales rep model.

5. Real-World Data and Evidence

Real-world data (RWD) and real-world evidence (RWE) transform innovations in the pharmaceutical industry.
RWD includes patient information like treatment data, health reports, and health status collected on a routine.
The research-intensive nature of the pharmaceutical industry ensures that data is reliable and of real value.
The RWD is enabled by the Internet of things (IoT)- the wearables and sensors restructure the functioning of the pharmaceutical industry.

6. Blockchain

The introduction of blockchain technology plays a significant role for pharmaceuticals at every stage of the production and distribution of drugs.
In general, the pharma industry stakeholders are secretive about their data due to their sensitive nature.
Blockchain has been explored to tackle the use of counterfeit medicines and substandard drugs entering the pharmaceutical supply chain and killing thousands every year.

The digitalization of transactions leveraging the blockchain promises a solution for tracking and hooking pharma transaction ecosystems.

7. Digital Therapeutics

Digital Therapeutics is a prominent way to deliver evidence-based therapeutic interventions with the help of software. It prevents, manages, and also treats physical, mental, and behavioural conditions.

These tech-driven non-pharmacological solutions are either stand-alone or anchored alongside devices, medications, or therapies. It helps every individual to have control over health and outcomes.

8. Curative Therapies

The pharma industry is experiencing a paradigm shift in the area of treating illnesses- from managing diseases to curing diseases.

Cell and gene therapies are the curative therapies that are changing the ways to deal with chronic diseases or difficult-to-treat conditions.

This eliminates the need for long-term treatments. In the case of gene therapies, genetic materials are introduced to the cells to either make a beneficial protein or compensate for the abnormal genes.

9. Precision Medicine

Precision medicine implies is from the idea to cater to each patient as a unique individual. Omic and data analysis advancements provide new insight into how a human body responds to a set of drugs.

Along with this, additive manufacturing in collaboration with other advancements makes personalized medicine a reality.

Different drug exposure models determine the pharmacodynamic and pharmacokinetic properties of drugs to get to the right drug dosage based on age, comorbidities, sex, and other clinical attributes.

10. Improved CyberSecurity

The pharmaceutical industry is a source of the most sensitive data and is in dire need of cybersecurity. It gives a possibility of rising data leakages, and it can emerge in different forms and sources.

The not-seeming-to-end technological advancements establish that the pharma industry is bound to face security risks.

With HIPAA and HITECH proposed modifications in effect in 2022 makes the pharma industry to re-strategise the impact of personally identifiable data for the proper functioning of an organization.

Reimagining Pharmaceutical Industry in 2022

The pharmaceutical industry is evolving in response to the evolving behaviour of customers, HCPs, and investors.

COVID-19 has not only reshaped the pharma industry's functioning but has also fueled up development aspects of the pharma industry trends- notably in digitalization and patient engagement[9].

If you are following recent trends in pharmaceutical industry innovations, brace up for 2022!

The 10 Trends Shaping the Future of Pharma:

The pharma industry has taken a big swing into digital transformation. All participants invest in digital health topics. But as with all trending issues, there is a lot of fuss that is hard to see through. As the medical community increasingly acknowledges the importance of digital health, the cultural shift we so often talk about is still a way to go. To change that, the first step is always getting to know what's coming.

In this article, we collected the trends changing the pharmaceutical industry.

And if you want to have a more in-depth analysis of the topic, read our related ebook, **Technologies Shaping the Future of Pharma!**

1). Have patients on the advisory board of pharmaceutical giants

As patients take their health and through that their future into their hands with the help of digital health, they also should be treated as equal partners in hospitals, pharmacies – and even pharma companies. Drug producers should have an advisory board including patients who have experience with the given company's products.

It would be easier to develop new products if the exact needs of the customers are well-known. Only with their help would it become possible to create a healthcare system that is futuristic even decades after the first plans were drawn.

2). Digital health strategy "around the pill"

Rather than focusing on traditional drug manufacturing and marketing, pharma companies will put more emphasis on new approaches relying on technology to appeal more to providers and payers. "Around the pill" is more than the production and the sale of drugs: it is about ***developing a drug and attaching digital health technology to it***.

These are often patient-support programs, that are often non-clinical solutions, that can boost patient outcomes and benefit the entire health system. These initiatives create win-win situations, with patients receiving more than just a pill, while pharma companies can build on the data and the feedback they receive – and the likely loyalty of patients who appreciate the extra care. If done well.

Good solutions however are not easy to make. There are only a handful of good examples, one of these is that of mySugr. The startup's approach for diabetes management is a gamified approach, wherein they reimagined diabetes as a Tamagotchi-like monster that can be tamed. By completing challenges, earning points and receiving personalized insights, the app incentivises patients to keep their glucose level at a desirable one. The idea was so good pharma giant Roche acquired mySugr in 2017 and kept the team to continue growth. The company went on to pair the app with its existing Accu-Chek Guide glucose meter to create the mySugr Bundle.

3). Digital pills

Digital pills and medications with embedded electronic circuits can be good solutions for specific patients with specific conditions. These refer to ingestible medications with embedded electronic circuits rather than smartphone logging apps.

For example, such pills could help with medication adherence in people taking medicines regularly. The first pill approved by the FDA was Abilify Mycite in 2017 (by since-dissolved pharma startup Proteus), a drug that was aimed at helping psychiatric conditions like bipolar disorder and schizophrenia. As a patient swallows the pill, the acidic environment in the stomach activates the pill's sensor, which thereafter begins to send Bluetooth signals to an external patch. It will then notify the smartphone app that the pill was taken. Such pills are game-changers for patients with severe conditions like schizophrenia and severe depression, as for them, missing a medication can have serious consequences.

As we wrote in our related article, The Present And Future Of Digital Pills, another company, etectRx gives patients more control over when monitoring starts. Their FDA-approved solution involves a removable lanyard rather than a patch, which patients can remove after taking their medicine.

4). In silico trials

In silico experiments are conducted by means of a computer simulation. Besides its time and cost-effectiveness, in silico trials completely circumvent animal testing and side effects on human and animal participants.

In silico trials can completely replicate human clinical research, according to a recent study. Research indicates that these trials are efficient. However, it was not until COVID-19 that these became more widely used. The pandemic broke down the reluctance of medical professionals against such use of technology, as the need for quick and effective trials was imminent.

5). Virtual reality against painkillers

Virtual reality (VR) is becoming a reality in hospitals as we speak. As a doctor, you could assist in the OR without ever lifting a scalpel. If you are a medical student, you could study the human body more closely and prepare better for real-life surgeries. As a patient with mental health problems, you could fight your possible fear of heights, schizophrenia or paranoia more successfully.

However, one of the most successful applications of medical VR is in the field of stress release and pain reduction for patients suffering from chronic pain. Perhaps pharma companies should consider stepping into the field instead of creating new types of painkillers. Brennan Spiegel and his team at the Cedars-Sinai Medical Center are experimenting with the technology. They even found a significant drop in pain scores in the case of VR therapies. Spiegel believes the future will be VR pharmacies with specialists prescribing the appropriate VR treatment to patients.

6. Precision medicine through pharmacogenomics

As the National Institutes of Health (NIH) formulated it, precision medicine is "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person." There are various trends in precision medicine connected to pharma. On the one hand, researchers experiment with cancer drugs that directly attack cancerous cells without damaging other tissues; for example in treating cervical cancer. On the other hand, medical experts try to incorporate genetics into the process of creating targeted therapies and personalized treatments. Pharmacogenomics is one way to go about this.

Pharmacogenomics is defined as the study of variability in drug response due to the genetic code. It argues that despite general sentiments, medications do not have the same effect on people. There are already some, who expressly recommend genetic testing before any prescription of e.g. Warfarin, a type of anti-blood-clotting drug takes place.

7). 3D printing drugs

Researchers worldwide are working on possible solutions: from a group that printed a miniature kidney, through technological solutions like BioAssemblyBot we wrote about earlier, to entirely new methods that can lead to patient-specific heart tissue printing. The list is long and set in a clinical setting.

UK-based FabRx believes they will be able to commercialize printed tablets within the next 5-10 years, and 3D printing will probably become available in every major hospital in the next decade. Whether we will also print out drugs at home or at least at the pharmacy on the corner of the street? The latter is more imaginable, but maybe in 20 years, 3D printers as home-based pharmacies will also not be considered elements of science fiction.

8). Medical decision-making with artificial intelligence (AI)

A.I. will soon revolutionise healthcare – through mining medical records, designing treatment plans, speeding up medical imaging, or even drug creation for that matter. Artificial intelligence-based strategies for drug development are on the rise and so is their adoption. A.I. makes finding new drugs cheaper and more effective.

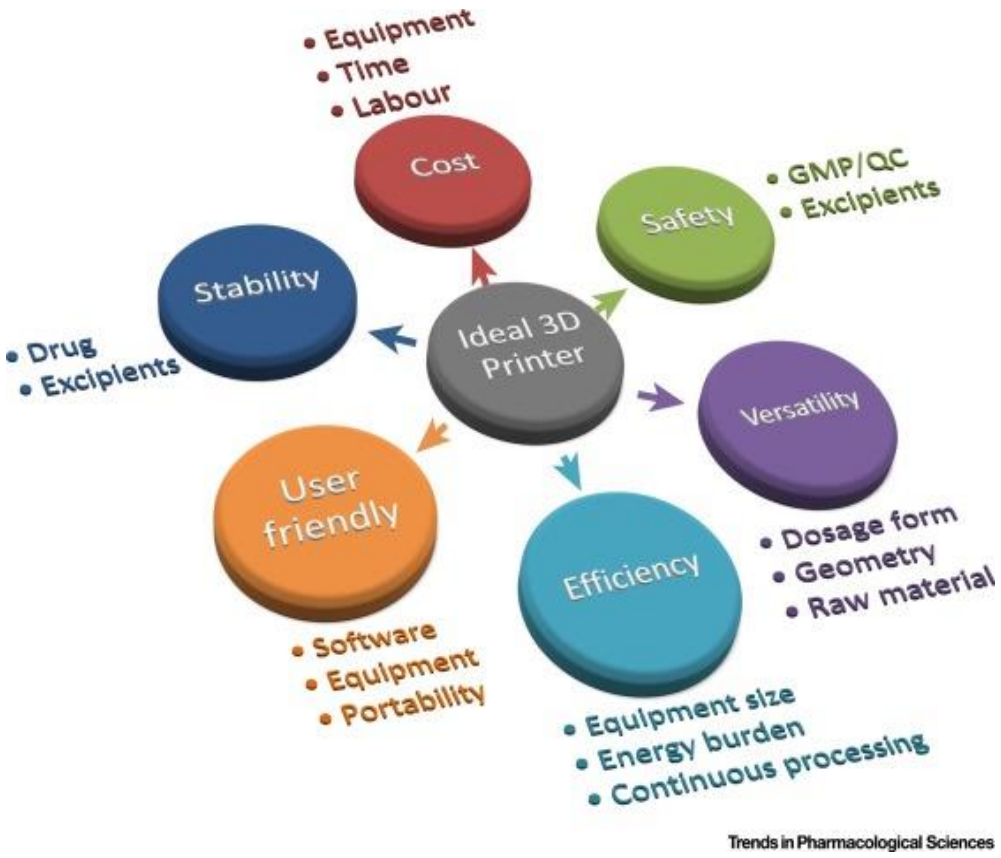
According to estimates, on average it takes about 12 years and $2.9 billion for an experimental drug to advance from concept to market. A.I. can downsize these numbers significantly.

9). Need for new FDA and drug regulations

I believe that there is a consensus in the medical community that regulations concerning drug production, moreover digital health devices or health apps are obsolete. Regulatory agencies are unprepared for the waves of digital innovation.

We could notice it with the appearance of the wearenotwaiting Twitter movement for patients suffering from diabetes. They started to use the so-called artificial pancreas without FDA or any other approval because the patients had the impression it works and they needed it. With the rapid innovation of digital health solutions, regulators need a more rapid response to get ahead of possibly dangerous DIY solutions.

Another example of regulations going after innovation is the case of direct-to-consumer genetic testing companies. They appeared approximately ten years ago on the market. However, in 2014 the FDA restricted 23andme's operations saying that the health information services were not clear or complete enough for customers. So, the genetic testing company scaled back its activity mostly to provide data about ancestry. They have linked together long-lost family members and have built family trees. In April 2017, however, the FDA re-approved 23andme's services, which aim to tell people to which diseases they are susceptible.



10). Augmented reality to make drug descriptions more fun

AR has many exciting applications in healthcare: nurses can find veins easier with an AR vein scanner, AccuVein or describe their eye condition better to their doctor through EyeDecide. There are already great signs that AR will enter the field of pharma soon. Look at drug descriptions, for example. Have you ever been curious about how a drug works in your body? Even if you got interested in discovering how the distant world of pills and medicaments work, I bet you lost all your enthusiasm after you read the boring and indecipherable drug description. Now, augmented reality is here to change it. With the help of AR, patients can see how the drug works in 3D in front of their eyes instead of just reading long descriptions on the bottle.[10-12]

Conclusion

Pharmaceutical innovations **create value to society by making it possible to generate improvements in patient health (net of treatment risks) that were previously unattainable**. It is the uniqueness of such health improvements that defines pharmaceutical innovations.

It's time to embrace what is crystal clear. Digital health is changing care, the practice of medicine and how pharma innovations reach patients.

Conflict of Interest; The authors declared no conflict of interest.

References

1. Sobocki P, Lekander I, Berwick S, Olesen J, and Jönsson B. Resource allocation to brain research in Europe – a full report. *Eur J Neurosci*. (2006) 24:2691–3. doi: 10.1111/j.1460-9568.2006.05116.x
CrossRef Full Text | Google Scholar

2. Tiwari S, Atluri V, Kaushik A, Yndart A, and Nair M. Alzheimer's disease: pathogenesis, diagnostics, and therapeutics. *Int J Nanomedicine*. (2019) 19:5541–54. doi: 10.2147/IJN.S200490
CrossRef Full Text | Google Scholar

3. Zibly Z, Shaw A, Harnof S, Sharma M, Graves C, Deogaonkar M, et al. Modulation of mind: therapeutic neuromodulation for cognitive disability. *J Clin Neurosci*. (2014) 21:1473–7. doi: 10.1016/j.jocn.2013.11.040
PubMed Abstract | CrossRef Full Text | Google Scholar

4. Khan IS, D'Agostino EN, Calnan DR, Lee JE, and Aronson JP. Deep brain stimulation for memory modulation: a new frontier. *World Neurosurg*. (2019) 126:638–46. doi: 10.1016/j.wneu.2018.12.184
PubMed Abstract | CrossRef Full Text | Google Scholar

5. Henze LJ, Koehl NJ, O'Shea JP, Kostewicz ES, Holm R, and Griffin BT. The pig as a preclinical model for predicting oral bioavailability and *in vivo* performance of pharmaceutical oral dosage forms: a PEARRL review. *J Pharm Pharmacol*. (2019) 71:581–602. doi: 10.1111/jphp.12912
PubMed Abstract | CrossRef Full Text | Google Scholar

6. Renfro LA, and Sargent DJ. Statistical controversies in clinical research: basket trials, umbrella trials, and other master protocols: a review and examples. *Ann Oncol*. (2017) 28:34–43. doi: 10.1093/annonc/mdw413
PubMed Abstract | CrossRef Full Text | Google Scholar

7. World Health Organization. *20 Million Children Miss Out on Lifesaving Measles, Diphtheria and Tetanus Vaccines in 2018*. (2019). Available online at: https://www.who.int/news-room/detail/15-07-2019-20-million-children-miss-out-on-lifesaving-measles-diphtheria-and-tetanus-vaccines-in-2018 (accessed September 18, 2019).
Google Scholar

8. Venter H, Henningsen ML, and Begg SL. Antimicrobial resistance in healthcare, agriculture and the environment: the biochemistry behind the headlines. *Essays Biochem*. (2017) 61:1–10. doi: 10.1042/EBC20160053
PubMed Abstract | CrossRef Full Text | Google Scholar
9. Zottel A, Videtič Paska A, and Jovčevska I. Nanotechnology meets oncology: nanomaterials in brain cancer research, diagnosis and therapy. *Materials*. (2019) 12:E1588. doi: 10.3390/ma12101588
PubMed Abstract | CrossRef Full Text | Google Scholar
10. Antoszczak M, and Huczynski A. Salinomycin and its derivatives - A new class of multiple-targeted "magic bullets". *Eur J Med Chem*. (2019) 176:208–27. doi: 10.1016/j.ejmech.2019.05.031
PubMed Abstract | CrossRef Full Text | Google Scholar
11. Kwon OS, Kim W, Cha HJ, and Lee H. *In silico* drug repositioning: from large-scale transcriptome data to therapeutics. *Arch Pharm Res.* (2019) 42:879–89. doi: 10.1007/s12272-019-01176-3
PubMed Abstract | CrossRef Full Text | Google Scholar
12. Vaccaro L. Green chemistry. *Beilstein J Org Chem*. (2016) 12:2763–5. doi: 10.3762/bjoc.12.273
PubMed Abstract | CrossRef Full Text | Google Scholar