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DIGITAL TECHNOLOGIES FOR BETTER PHARMA TOMORROW

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Abstract

The digitisation of healthcare has given patients greater influence than ever before. Digital health solutions are therefore now essential to meet the needs of more empowered patients who are taking an active role in their own treatment choices. A variety of platforms and systems that use technology to improve healthcare delivery are included in the field of digital health. Digital therapeutics (DTx) is a subset of digital health solutions that offers software-driven therapeutic treatments based on evidence for the management and prevention of illnesses. A thorough overview of DTx, including its uses and functions in healthcare and related regulatory aspects, is what this review seeks to present. Demonstrated how developments in online platforms, blockchain, and artificial intelligence are changing pharmacy services and education.

Keywords: digital therapeutics, digital medicine, app-based healthcare, and regulatory aspects.

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**INTRODUCTION**

Today's world views drug development as a time-consuming, costly, and risky endeavour. Global pharmaceutical and life sciences companies have made significant investments, yet overall research and development (R&D) productivity has significantly decreased. [1] The healthcare industry is moving toward a more digital world as ideas like precision and customized treatment gain traction. With the rise of social media platforms, smartphones and mobile applications, wearable technology, cloud-based data platforms, real-world evidence studies, and the like, digital health has exploded globally in the past ten years. In this sense, "digital health" refers to any technology that involves individuals in their health and well-being, including wearables, smart devices, telehealth, mobile health (mHealth), health information technology, and customized medicine [2]. "Digital Therapeutics" (DTx) is an emerging phenomena in the digital health space that involves innovative models being researched, employing open source engineering, and optimizing the capabilities of experts from traditional healthcare settings.

DIGITAL THERAPEUTICS: WHAT IS IT...?

A subset of digital health, which encompasses a range of tools, goods, and services from the healthcare and wellness sectors, is called digital therapeutics (DTx). First used in their peer-reviewed paper in 2015, Sepah et al. provided a formal definition of "digital therapeutics" as "evidence-based behavioural treatments delivered online that can increase accessibility and effectiveness of healthcare." [3] "Delivering evidence-based therapeutic interventions to patients that are driven by software to prevent, manage, or treat a medical disorder or disease" is how the Digital Therapeutics Alliance (DTA) defines the DTX. To improve patient care and health outcomes, they are applied either alone or in combination with drugs, equipment, or other therapies [4].

DTx's HISTORY

Dr. Joseph Kvedar of Boston, USA, spearheaded a program in 1995 to teach students how to build and use technology to provide care outside of the conventional hospital or doctor's office setting, proposing the "one-to-many model of care." In addition to improving patient care with fewer resources by offering access, convenience, and efficiency, the goal was to broaden the scope of physicians by overcoming time, location, and staffing constraints that limit healthcare

delivery. Dr. Kvedar's endeavour may be considered one of the first by researchers in the field of digital health/DTx. As early as 2000, there was evidence in the literature that using digital products could improve health outcomes [5].

Relationship between digital health and digital medicine.

A wide definition of digital health is the integration of technology and healthcare. To prevent misunderstandings among digital health stakeholders and the producers and developers of these goods, it is crucial to distinguish between digital health, digital medicine, and DTx. This will improve the products' market positioning and usefulness. [6] Figure 1 shows how these three linked concepts relate to one another. Additionally, they have differing standards for clinical evidence and regulatory monitoring. Digital health encompasses a wide range of platforms, systems, and technologies that interact with customers for wellness, lifestyle, and health-related objectives. Clinical activities can be supported by the collection, storing, and transmission of health data by digital health entities. Health information technology, telehealth systems, systems that employ consumer health data, and clinical care management tools are a few examples of digital health systems. Distinguishing digital health from digital medicine. On the other side, digital medicine uses hardware or software applications that are usually backed by data to assess or improve human health. As previously stated, evidence-based therapeutic interventions that prevent, manage, or treat a disease or medical disorder are included in DTx. Digital sensors, wearable technology, some virtual reality, and artificial intelligence devices are a few examples of DTx applications. However, it might be incorrect to assume that digital health products are risk-free in comparison to digital medicine or DTx products. Commercial digital health technologies might have their own dangers, but the latter two depend on more evidence and regulatory control because of the increased clinical risk. Because it may assist all stakeholders fully comprehend the purpose and clinical value of these products, the classification of products under digital health, medicine, and therapeutics additional effort to examine their potential to better healthcare delivery [7]

HOW DOES DTX WORK

With the use of remote monitoring and behavioural modifications, DTx is a new class of applications that assist treat illnesses and produce better, long-term health results. These applications are designed to produce positive results; for instance, they can motivate patients to follow specific medication or diet and exercise schedules. DTx applications are designed to treat specific disease conditions, especially significant chronic diseases like diabetes, cardiovascular problems like hypertension, and pulmonary diseases like COPD. This is the main distinction between DTx and wellness applications [8].

DTX IN INDIA

In order to improve their market position and better handle the shifting market dynamics, numerous Indian pharmaceutical businesses are currently altering their business structures, strategies, and product portfolios. Businesses are now aware of the amazing value that DTx products and services provide. It is thought that DTx services could lower the cost of manufacturing drugs while also benefiting insurers by enabling them to tailor their offerings to the demands of their clients. DTx is still uncommon in India, nonetheless, and several businesses intend to invest and enter the DTx market [9].

APPLICATIONS

There are more and more DTx applications being developed for the management of mental health conditions. Cognitive-behavioral therapy (CBT) in digital form is showing encouraging outcomes in the treatment of anxiety and depression. Additionally, CBT is rapidly expanding into new fields, such as substance abuse disorders. Similar drugs are also being developed to treat sleeplessness and schizophrenia. For example, a CBT-based online self-care program for insomnia has demonstrated benefits in mental health and insomnia symptoms. By facilitating proactive quality control, predictive maintenance, and real-time monitoring, the incorporation of digital technologies into pharmaceutical manufacturing has the potential to greatly improve risk management [10].

1. Have patients on the advisory boards of major pharmaceutical companies.

In this post, we compiled the trends that are transforming the pharmaceutical sector. For a deeper look at the subject, check out our associated publication, Technologies Shaping the Future of Pharma!

Top 10 technologies in pharma

1. Include patients on the advisory boards of major pharmaceutical corporations. Hospitals, pharmacies, and even pharmaceutical corporations should regard patients as equal partners as they take control of their health and, consequently, their own destiny, with the aid of digital health. An advisory board including patients who have used the company's medicines should be established by drug manufacturers [11].

2. "Through the pill" digital health strategy

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.

There are very few excellent instances, and my Sugre is one among them. The startup's gamified approach to diabetes treatment recasts diabetes as a tamagotchi-like monster that can be subdued. The software encourages users to

maintain a desirable blood glucose level by rewarding them with challenges, points, and personalised information. Because of how brilliant the idea was, the pharmaceutical behemoth Roche bought my Sugr in 2017 and retained the team to help it develop. The business then developed the Sugr Bundle by combining the software with its already-existing Accu-Chek Guide glucose meter [11].

3. Digital Medications

For certain people with particular diseases, digital pills or drugs with incorporated electronic circuits may be good options. Instead of smartphone logging apps, these are ingestible drugs with electronic circuits built in them. For those who take medications on a regular basis, these pills may aid in medication adherence. Ablify Mycite, a medication developed by the now-defunct pharmaceutical startup Proteus, was the first tablet to receive FDA approval. It was intended to treat mental illnesses like schizophrenia and bipolar disorder. The sensor on the pill is activated by the stomach's acidic environment as the patient consumes it, and it then starts sending Bluetooth signals to an external patch. The smartphone app will then be informed that the medication has been consumed. These medications are revolutionary for individuals suffering from serious illnesses like schizophrenia [11].

4. In silico experiments

A computer simulation is used to carry out in silico experiments. In addition to saving time and money, in silico experiments totally avoid animal experimentation and the negative consequences they can have on both human and animal subjects. A recent study found that human clinical research may be fully replicated in silico trials. Studies show that these trials are obviously effective. However, these weren't employed more frequently until COVID-19. Because rapid and efficient studies were urgently needed, the pandemic dispelled medical professionals' hesitation to adopt such technology [11].

5. Virtual reality in opposition to pain killers

As we speak, virtual reality (VR) is starting to appear in hospitals. You may help in the operating room as a doctor without ever using a scalpel. You could better prepare for actual procedures as a medical student by studying the human body in greater detail. You might more effectively combat your potential paranoia, schizophrenia, or fear of heights as a patient with mental health issues. However, helping patients with chronic pain manage their stress and pain is one of the most effective uses of medical virtual reality. Instead of developing new kinds of medications, pharmaceutical companies might want to think about entering the market. [11]

6. Utilizing Pharmacogenomics For Precision Medicine

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," according to the National Institutes of Health (NIH). Precision medicine has several trends that are related to pharmaceuticals. In order to treat cervical cancer, for instance, researchers are experimenting with cancer medications that target malignant cells directly without causing harm to surrounding organs. Medical professionals, on the other hand, attempt to use genetics in the development of tailored therapies and focused treatments. One approach to this is pharmacogenomics. The study of genetically determined variations in drug response is known as pharmacogenomics. It makes the case that drugs don't always have the same impact, despite popular belief. Some people currently specifically advise genetic testing before to using anti-blood-clotting medications like Warfarin. [11]

7. 3D Printing Drugs

From a team that created a small kidney to technology advancements like BioAssemblyBot, which we previously discussed, to completely novel techniques that could result in patient-specific cardiac tissue printing, researchers from all around the world are working on potential solutions. The lengthy list takes place in a medical setting. Within the next five to ten years, UK-based FabRx anticipates being able to commercialise printed pills, and within the next ten years, 3D printing is likely to be accessible in all major hospitals. Will we print out medications at home as well, or at the very least, at the local pharmacy? The second is more plausible, but perhaps in 20 years, home-based pharmacies using 3D printers won't be seen as science fiction either.

This leads to the initiation of personalized medicines where medications are tailored to patients or designed more particularly for them as part of a group of genetically, physiologically or pathologically similar patients [12]. With a mantra of "one size does not fit all", its goal is to dispense the best drug at the best dose, for the precise indication of the patient, at the correct time personalized medicine promises are more precise medications. These are more safe and efficacious, improve patient compliance, and are cost effective [13]. Three-dimensional printing, also called 3D printing or additive manufacturing, involves the deposition of material in a layer upon layer manner to gradually construct a solid model. It uses a computer-aided design (CAD) software which transfers the necessary signals to a 3D printer, which then converts the computerized digital model into two dimensional (2D) sections, which generates solid layers to build up the required objects [14]. In conventional manufacturing processes, also, the doses cannot be manipulated easily according to the patient needs. 3D printing can transform healthcare through personalized medicine, thus improving patient compliance by tailoring the medication to the patient. This can be achieved through on-demand manufacturing in clinical settings to offer the best medical care [15]. There is a considerable amount of literature review on 3D printing and its application in drug delivery. However, there are only limited number of articles which explain the various technologies involved in 3D printing and their applications in pharmaceuticals, along with their use in personalized medicine and their ability to tend to various populations

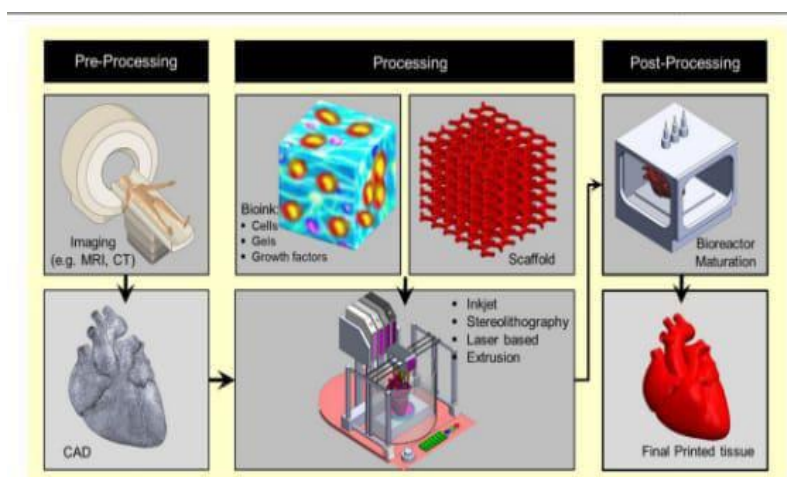


Fig 02: 3D Printing of Drugs

ARTIFICIAL INTELLIGENCE (AI) IN MEDICAL DECISION-MAKING

By accelerating medical imaging, creating treatment plans, mining medical information, and even creating new drugs, artificial intelligence has been completely changing the healthcare industry. Adoption of drug development techniques based on artificial intelligence is growing. AI improves the cost and efficacy of medication discovery. An experimental drug's journey from concept to commercialisation is estimated to take an average of 12 years and \$2.9 billion. AI can drastically reduce these figures.

AI in research and development

AI offers a significant advantage in automating the collection and analysis of data, particularly in pharmaceutical research and development (R&D). It enables the integration of diverse data sources, such as electronic health records, administrative records, and health surveys, resulting in a more comprehensive and precise data collection and management process. Consequently, this enhanced data handling capability leads to more reliable and robust trial results [16].

AI in Pharmaceutical manufacturing

Control (APC): It enables real-time dynamic control of manufacturing processes to attain desired outputs. The integration of AI methods with real-time sensor data allows the development of process controls that can anticipate the progression of the manufacturing process. By combining AI techniques with a profound comprehension of the chemical, physical, and biological transformations occurring during manufacturing, APC approaches are projected to gain widespread acceptance and have already been implemented by various pharmaceutical manufacturers [17].

New FDA And Medication Restrictions Are Required

In my opinion, the medical community as a whole agrees that laws pertaining to the manufacture of drugs are out of date, as are digital health tools or applications. The waves of digital innovation are overwhelming regulatory bodies. The emergence of the # we are not waiting Twitter movement for diabetic patients allowed us to observe it. Because the patients believed it worked and they required it, they began using the so-called artificial pancreas without FDA or other approval. In order to stay ahead of potentially hazardous do-it-yourself solutions, regulators must react more quickly to the rapid invention of digital health solutions. Recently, generative AI has entered this unique regulatory debate. [14].

USING AUGMENTED REALITY TO ADD FUN TO DRUG EXPLANATIONS

Augmented reality (AR) has a lot of fascinating uses in healthcare. For example, nurses can use an Augmented reality (AR) vein scanner, such as AccuVein, to detect veins more easily, or Eye Decide to better explain their eye condition to their doctor. There are already encouraging indications that AR will soon make its way into the pharmaceutical industry. Take, for instance, the descriptions of drugs. Have you ever wondered how a medicine affects your body? I bet that after reading the dull and incomprehensible medicine description, you lost all interest in learning more about the far-off world of pills and medications. Augmented reality is coming to make a difference. Instead of merely reading, patients can use AR to see how the medication works in three dimensions their eyes [14].

Digital therapeutics technologies;

The four primary types of key technologies in DTx are as follows:

1. Data Collection and Preprocessing
2. Data Analysis
3. Human Computer Interaction
4. Recommendations System

User customization is closely related to a recommendation system (RS) that provides a personalized treatment plan based on user data. Generally speaking, RS provides users with personalized solutions using content-based algorithms,

collaborative filtering, or hybrid filtering. It is necessary to continuously improve hybrid filtering recommendation systems by extracting different elements from the input using machine learning techniques [18].

ADVANTAGES IN dtx

1.Identity; -product is deemed to be misbranded, adulterated, or both if its identity and identification criteria do not meet standards. Each DTx product has a unique code that serves as its identity. Upgrading and/or improving the code may not be considered a new DTx because the functionality and manner of operation are unchanged. As a result, the function or output of the code truly determines its identity. Specifically, a collection of anticipated inputs, outputs, and behaviours could be used to perform identity checking on a DTx, its digital excipients, and its digital application programming interface (API).

2.Strength: -concentration of an active pharmaceutical ingredient (API) in a medication is determined by quantitative testing, often known as strength testing. There are two primary approaches to assess the strength of DTx products: [19] how frequently the patient is exposed to the DTx product. These two positions are not mutually exclusive. Over the course of the DTx's life, it is crucial to maintain its potency and make sure the patient receives the recommended dosage.

Performance: -The pharmacopeial approach defines performance as the extent to which the pharmaceutical product being sold has the physical characteristics required to achieve the targeted therapeutic effect at the designated site. It's critical to show that the DTx product performs consistently throughout its lifetime. For DTx, efficacy, safety, user engagement and adherence, stability, dependability, data accuracy, interoperability, and patient satisfaction are the criteria for consistent product performance

Disadvantages

1.Data security and privacy: - Mobile health apps gather vast amounts of data, whether or not they contain personal information. Security and privacy are crucial concerns in the realm of digital health since hackers are likely to target sensitive health data [11].

3.Public Awareness:- Since many patients and medical professionals are hesitant to change and are not fully aware of the benefits of DTx, it is imperative that people are educated about both the advantages and disadvantages of the treatment.

4.Cost And Availability: The public wants new treatments to be accessible and affordable, but the cost of pharmaceuticals continues to be a contentious issue. It might be difficult to strike the right balance between fair pricing and continuing to invest in R&D.

CONCLUSION

The goal of digital therapeutics is to improve the global healthcare system by offering more accurate diagnosis, individualized care, and more effective medications. Digital therapies, which offer customized, effective, and easily accessible treatments by fusing cutting-edge technology and clinical expertise, mark a dramatic change in the healthcare sector. Digital therapeutics might save millions of dollars in medical expenses by providing safer and more cost-effective alternatives to conventional treatments. Furthermore, the modern economy, society, enterprises, and labor market have all seen substantial changes since the start of the digital revolution.

AUTHOR CONTRIBUTIONS

All authors are contributed equally

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