Utilising Digital Strategies to Improve Personalised Medicine Delivery through Additive Manufacturing

By

CHIEDOZIE CHIBUIKE

3106105

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Candidate Declaration

Candidate Name: Chiedozie Chibuike

I hereby declare that the dissertation entitled " Utilising Digital Strategies to Improve Personalised Medicine Delivery through Additive Manufacturing" submitted for the degree of MSc in Digital Transformation (Life Science) is a research work carried out by me, and that all sources used have been acknowledged by means of complete references.

SIGNED: COCHIEDOZIE

DATE: 28th August 2023

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List of Abbreviations

AM	Additive Manufacturing
PMT	Personalised Medical Therapy
3DP	Three-Dimensional Printing
CIJ	Continuous Inkjet printing
DoD	Drop-on Demand Inkjet printing
FDM	Fused Deposition Modelling
PAM	Pressure-Assisted Micro-syringes
SLS	Selective Layer Sintering
FDA	Food and Drug Administration

Abstract

The modern healthcare system faces a paradigm shift with the introduction of new technologies. A growing change in dynamic from a one for all manufacturing approach to a patient centred approach for healthcare has increased, with greater understanding in pharma gene theory and a slow rising demand for personalised healthcare services. Additive manufacturing is a well-established process in many industries, but relatively novel within the medical field. Its recent success in drug manufacturing along with the increased understanding of pharmacokinetics and pharmacogenomics allows for the convergence of 3D printing and personalised medicine opening new horizons for tailoring medical treatments to individual patients. However, the effective implementation of 3D printing in this context necessitates a robust digital strategy that encompasses design manufacturing, ethics, data management, and regulatory considerations.

This paper works to critically investigate the broader implications and possibilities arounds digital strategy implementation by healthcare organisations looking to adopt additive manufacturing technologies as their main digital tool in emphasizing personalised Medicare services. The study looks to review opinions from various sources of literature, from articles, journals, seminars etc idealising trends, events and limitation towards a working digital strategy promoting personalised healthcare. Evidence of review show a lack of digital identity or guideline necessary but provides practically to the manufacturing of personalised 3D printed drugs.

The paper works with a positivist study philosophy, developing a quantitative questionnaire to survey the opinions of industry experts around Ireland. It was an online questionnaire prepared using Microsoft Forms consisting of closed ended questions to a range of experts in the medical field, from doctors, nurses, Professors, Regulatory experts, and Business Directors. Opinions gathered was compared to secondary sources.

The result of the study took considerations from both secondary and primary sources in generating a 4-step process in developing a digital path for organizations utilising additive manufacturing. The study also reflects on conceptual implementation ideas and the benefits and limitations faced in the process.

Keywords: 3D printing, Additive manufacturing, Personalised medicine, Digital Strategy, Industry 4.0, Digital Ethics.

1. INTRODUCTION

The world as we know is an ever-growing bubble of change, and on result, history tells us through the length and wealth of our improvements in our everyday lives, reaches for innovation and depth of new or modernised technology as claim for it. As our history looks to define our future once more, the race to evolve and adapt sets a push for our innovative limits, pushing the industrial world into what some recognise as the Digital Age. To some with a plan it's a picture away from reality, and to others a maze to discover, however the need for an ideal strategy is necessary to explore the many unknowns or solutions to be discovered in this New Era.

In discussing journey into the Digital Era, a dive into the story of growth brought through by the Industrial Revolutions would follow. In short it describes the transition of industries over history from manual to automated and now transitioning to smart or data driven industrial operating processes.

The first industrial revolution begun in the late 1700 with the invention of the steam engine. This provided mechanised power that led to increased levels of production between the late 1700 and 1800. It allowed the transition of societies to grow from simple farming and feudal colonies into a manufacturing nucleus. This transition included the use of coal as the main energy while trains were the main means of transportation. Textile and steel were the dominant industries in terms of employment, value of output, and capital invested [Xu, M. et al 2018].

The second industrial revolution saw the amassment of new technology and management practices that allowed the use of assembly lines to promote mass production of goods and services. This revolution began in 1900 with the invention of the internal combustion engine that led to rapid industrialization using oil and electricity to power these production processes.

The third industrial revolution that begun around 1960 was characterized with the advent of computers, and the implementation of new electronics and information technology. This brought about the possibility for automation production which enabled mass customization. Some consider this era to be the genesis of the Digital Age, with newer technology allowing companies evolve in their means of operation creating data of processes and results. However much of these data and information presented haven't truly been utilised to its real potential. Major and minor crisis events such as the Covid 19 pandemic of recent, and climate concerns, have led to new laws and industrial motives for a reinvention on how companies do things. In this, the introduction of new technologies such as AI models, Robotics and additive manufacturing processes are being utilised to solve common industrial problems such as sustainability, reduce cost or inefficiency and implement green operational standards.

The fourth industrial revolution is the idea that solves and challenges the digital era into a place for digital transformation. It is based on the amalgamation of these new technologies working to utilise data and advance all industrial sectors modes of practice and manufacturing. They involve the mass digitization of business through big data analytics, advanced robotics, adaptive automation, additive and precision manufacturing (e.g., 3D printing), modelling and simulation, artificial intelligence, and nano-engineering of materials. In result, its preliminary evidence show early works of factories able to reduce waste, produce more goods in shorter amount of time and a reinvent of people's way of work and lifestyle.

This industrial era has proven to increase value production within the Life Science and Medical Industry, as they push the bar towards attaining their goal. The Life Science and Medical industry aim towards the understanding of biological life with the provision of health care services that prevents problems, maintains, and improve the health and lifestyle of patients. To achieve this, the concept around the wider individualization of patient treatment remains a core objective and a direction heavily challenged by the medical field towards the preservation of life and increased welfare.

The Covid 19 pandemic was a global crisis event that took the world by storm, imposing strains to people's health, lifestyle, and the global economy market. It was an event that really revealed the gaps and poor function of the medical sector of many countries. Despite all that, a united push towards a drug/vaccine solution was enforced and led by top scientist and pharmaceutical sector. This united front mobilized and brought about many elements of the drug discovery and questions on existing development process [Aghila Rani, K.G., et al 2021].

Reform in strategies held by organisations in the life science industry have had to change post Covid 19 pandemic to seek therapies that address most pressing public health issues. A chunk of this newly led agenda is pushed by multiple industry 4.0 medical programs that some would better recognise as Pharma 4.0. Many companies within the industry look to the incorporation of digital technologies as tin their attempt to develop an agile proactive mean of operation. One of major trend affecting the pharmaceutical industry would be the manufacturing process of drugs moving from the traditional batch processes to a continuous manufacturing process. In materialising this concept, a change ideology to accommodate newer technology for process standardization, understanding and validation are being explored through the wider Industry 4.0 agenda. Another challenge that gained higher relevance post pandemic was patient drug responses. Drug Responses amongst patients remains a well-known issue within the medical sector, and as such has been a factor that has led to poor treatment and hospitalizations worldwide. It provided a major challenge in discovering and the administering ideal remedy to handle the pandemic with reports of adverse or damaging effects to patients. Drug Response has always been an issue largely due to no clear biomarkers within patients that allows for doctors or scientist to identify which patient responds positively or negatively to medication and their different dosages [Shastry, B.S., 2006].

Given these issues, the individualisation of patient treatment that provides personalised healthcare remedies has been extensively researched and investigated for ways to reach the wider public by medical corporations. Tailored prevention and care to individuals describes the main aim of personalized medicine. In this way, people can improve their health or avoid chronic diseases, using information on their genetics and lifestyle. It poises as the solution to reduce or eliminate bad drug response in patient and improve public health of patients that allows better crisis management as seen during the Covid 19 pandemic.

The idea of Personalised medication festers the possibility to remodel manufacturing thoughts around drug delivery systems. Drug delivery refers to approaches, systems, technologies, and formulations for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect. Drug delivery has progressed significantly throughout the years, from immediate-release oral dose forms to targeted-release drug delivery methods. Changing the medication release profile to regulate absorption, distribution, metabolization, and elimination of the drug, remains a critical component for improving product effectiveness and safety, as well as improving patient compliance [Goole, J. and Amighi, K., 2016]. The need for change in current pharmaceutical sector business models apparent and as mentioned is driven by global regulatory reviews, novel manufacturing processes, and consumer trends. This is with a focus on the innately expensive research costs, high-risk capital-intensive scale-up, and the conventional centralized batch manufacturing paradigm [Goole, J. and Amighi, K., 2016].

Additive manufacturing presents itself as one of the more popular digital enablers of the industry 4.0 agenda. Most known with its industrial production name 3D printing, it is a computer-controlled process that involves the creation of three-dimensional objects through layers depositions of materials. It is a common technique adopted by many industrial fields such as the aerospace, automobile, and civil engineering sector. It is one of the digital technologies paving the way for a multitude of solutions from customisation to distributed manufacturing, relieving company supply chain strains and promoting quicker Research and Design programs. It made way into many manufacturing process and is heavily studied of its application in the medical industry. So far, it's more actively used in the testing and manufacture of medical device component parts but is being researched and tested for concept ideas involved with drug manufacturing. The technology of 3D printing can reshape the entire sectors and alter how manufacturing processes are organized.

This research shines a light on 3D printing technology, highlighting its potential in revolutionizing the manufacturing of tablets. It provides different design freedom as well as reduce the time for new tablet models to reach the market. In contrast to conventional mass-manufacturing techniques like tableting and encapsulating, 3D printing would allow for printing of dosage forms on demand and push actualisation for personalized medical care.

Rapid prototyping is an agile strategy used that uses 3-dimensional prototypes to create a product or feature for testing and optimization of characteristics like shape, size, and overall usability. It was naturally accepted approach that has soon become essential in research and development area to fit with actual industrial directions of reducing both time and costs in the early stage of a novel manufacturing concept, reducing the inherent risk of new development to fail at later stages. Originally, RP was developed to produce prototypes of new products to increase the speed of production significantly, especially during the development stage. Today, Rapid prototyping could easily be confused with the general term "3D printing process", which is one of many existing Rapid prototyping techniques [Goole, J. and Amighi, K., 2016]. As a result, it is preferable to describe Rapid prototyping as an umbrella term that covers a variety of manufacturing techniques that use three-dimensional computer-aided design (CAD) data and don't need tooling.

Digital disruption has become a phenomenon of the 21st century transforming all known traditional industrial contexts, effecting all levels of business and societal function. This disruption is an embrace to digital solutions in organizations which require systematic changes of "working, roles and business offering". [Kraus et al. 2021]. The COVID-19 pandemic forced a faster push into global digital operations in many industrial sectors. One in which digital tools have become necessary to every interaction, forcing both organizations and individuals further up the adoption curve overnight. Now organisations aim to meet a world in which digital channels become the primary (and, in some cases, sole) customer-engagement model, and automated processes become a primary driver of productivity. The medical and healthcare industry are not strangers to this influence with targets to attain agile ways of working, and a prerequisite to meeting seemingly daily changes to improve patients' health and lifestyle. Following this, the study holds significance in presenting a short step for organisations navigating through the digital era. Organisations with an incentive towards personalised Medicare have a niche template for discussion into the utilisation of additive manufacturing possibilities.

1.1. Research Aims and Objectives

This research aims to review a digital strategy that promotes personalised medicine therapy, through the model utilisation of additive manufacturing techniques. The objectives of this research include the following:

- To review extensive literature on the use and limitations presented by Personalized Medicine
- To review extensive literature on existing Additive manufacturing techniques for personalized medicine manufacture, understanding the possibilities and limitations associated with the current implementation.
- To identify key digital enablers/technologies that can support the delivery of personalized Medicare using Additive Manufacturing.
- To assess the feasibility and scalability of implementing a digital strategy utilizing additive manufacturing for businesses

1.2. Research Questions

The generated questions are expected to be answered by the end of the study, to provide solution and way forward towards realizing these set goals. The research questions are:

- To what extent is personalised medicine utilized?
- What are the current limitations and challenges associated with the use of additive manufacturing?
- How does the use of additive manufacturing improve personalised medication and its impact on patient outcome?
- How does a digital strategy help overcome challenges presented by personalised medicine and additive manufacturing?
- What ethical and regulatory considerations must be considered when using additive manufacturing in personalised medicine

1.3. Thesis Structure

In review to the structure of this paper the study would be discussed in five different chapters comprises of introduction, literature review, research methodology, finding and discussion and finally recommendations and conclusion.

Chapter 1 provided an introductory summary into aspects of the study, highlighting the research aim, objectives and research questions set.

Chapter 2 presents critical work on a structured and logical dissection of existing literature towards the use of personalised medicine and additive manufacturing. It delves at the history on both topics through research, recognising the evolutionary growth and intersecting point of ideas from scholars to industrial practitioners of the concept. Evidence towards the digitisation of this process is also investigated through literature with trend highlighted towards business practises of how personalised medicine is used and additive manufacturing is utilised in this field. Core literature on the understanding of business strategies and digital strategies is also covered within this section.

Chapter 3 expands on the reasoning behind the research methodology used throughout the study. A focus on the research approach, strategy, data sourcing, collection and analysis is reviewed along with ethical considerations.

Chapter 4 present a descriptive analysis of results generated from the quantitative primary research data, along with a critical analysis of data and literature to identify relations. An optimised concept of implementation of additive manufacturing to a business is then presented based on literal findings and analysed results.

Chapter 5 is a conclusive thought on findings following analysed results, along with recommendations for future research.

2. LITERATURE REVIEW

A critical review on existing literature following keywords formed over the main subject of discussion around the study title would be summarised in this chapter. The focus review narrows down on studied trends and challenges observed and faced in the attempted execution of personalised medicine. A further review into the use of additive manufacturing in the medical field and its role and techniques towards enabling personalised medical services. Results and studies on successful practitioners of the process highlighting gaps in study and their limitations.

2.1. Personalised Medicine

Personalised Medicine is an idea to medical practice that takes account of personal aspects of a patient's profile to account as a framework for treatment planning. Some of this would including a use of their genetic make-up, biomarkers, medical history, ethnicity, environmental factors, and behavioural choices to deliver tailored treatment. It is a notion of patient-centred care, that moves away from the traditional healthcare dynamic of a one-size-fits-all treatment service. It is fuelled from the improved understanding of pharmacokinetics and pharmacogenomics within the medical sector along with new technology to aid the research, design, and manufacturing possibility.

Its history is not so much about development of the concept of "personalization" but about the evolution and increasing precision of diagnosis and treatment. It was an idea of treatment that can be traced back to the fifth century, 2400 years ago, introduced by the Hippocrates. Book written by Gordon & Kolsov, 2011 touches on their influence on the concept idea from their early study of medicine that looked to the connection between one's humor and their human anatomy. These humors in reference accentuates to one's interaction with their environment and is documented in concept of four elements that are the Sanguis/blood (air), phlegm (water), choler (fire) and melancholia (earth). The book records the diagnosis of diseases in this era as an imbalance between oneself physiology and their humours. What was recorded to be their missing factor was the lack of ability to connect observation and understanding of the real underlying reasons for diseases to the basic chemical and biological factors.

The goal of personalization in medicine has never changed, and in every era of medicine new knowledge and tools used to describe and diagnose diseases have been developed. From the metaphysical to the physical, the cellular to the molecular and most recently, to a system-level understanding of the interactions between molecular events and higher-level phenomena, such as cognition and behaviour. The change of crediting mental disorders to supernatural causes, to understanding them through brain imaging and the actions of neurotransmitters shows progresses in medical diagnostics [Gordon & Kolsov, 2011]. A trace in history of personalized medicine from ancient times to the present, clearly shows the critical shift in what may now be known as the post-genomic era. Using genetic and molecular diagnostics and other markers of functional significance, we are on the verge of accurately predicting whether someone will develop an illness many years in the future, respond positively to treatment, or suffer a serious reaction to a drug. The arrival of such advanced medical forecasting means that other elements of the health care and medical system will evolve. The technology, as well as laws protecting privacy, systems of payment, regulatory guidelines, physician and patient education, and ethical frameworks would need to be referenced and adjusted to suit the coming change. [Gordon & Kolsov, 2011]

The current imitation of personalised medical services is well summarised in the journal article by [Englezos et al., 2023] and is said to result from the pharmaceutical production methods used by most manufacturers. The current method is batch manufacturing where an Active pharmaceutical ingredient (API) is synthesised and tested off-site and then shipped to a secondary location for blending with required excipients before they undergo various production line processes needed for the product type (Hock et al., 2021). This process leads to the make of predefined commonly used doses that packaged accordingly and shipped to pharmacies and hospitals worldwide. Though the process has largely contributed to the provision of cheap and fast medication, the quality is questioned and proven not completely beneficial for patients and pharmacist. O'Connor and Lee (O'Connor and Lee, 2017) found inter-patient variation of up 10–30 fold exists between patients taking the same dose and this has led to estimated and complex prescriptions, some wasteful such as splitting tablets or multiple dosage for patients to compensate. These methods raise concerns for patients, with the exposure to compounds that could treat the diagnosed disease but at the further detriment to the patient's health following adverse drug reactions. The Food and Drug Administration (FDA) simultaneously raised its concerns about current quality compounding guidelines following the death of 60 patients due to contaminated drugs from a pharmacy store (US Food and Drug Administration FDA, 2020 [Englezos et al., 2023]

Another concern shown with the process is the vulnerability of mass-produced pharmaceuticals to international supply chain. The COVID 19 lockdown was a period that exemplifies the issue with its significant impact on the global medical supply chain. For example, Australia experienced a 300% rise in drug shortages between 2019 and 2020 [Englezos et al., 2023]. The drug shortages presented a limited pool of options for pharmacist compounding prescriptions for patient therapies. Compounding allows for individualisation of dose and dosage form, shape, colour, and taste. It also provides a solution to patients that have reason to avoid certain excipients. [Englezos et al., 2023]

Industry 4.0 is the term eagerly used in identifying the fourth industrial revolution, that pertains for new level of organization and control over the value chain of material life cycle in all sectors. It is a large-scale change which foresees a digital transformation of manufacturing outcomes, resulting in smart factories and supply chains. It is also geared towards increasing individualized customer requirements and sustainability. With the life science and healthcare industry, this area is largely affected by the motion, and with advancement in technology over many eras its led to conceptual ideas and medical practice such as Personalised Medicine to be brought to near reality on a large scale. The envisages Industry 4.0 factories and supply chains encompasses goods and machines being connected to the internet, communicating with each other, exchanging, collecting, and analysing data, and coordinating processes in a distributed fashion. This creates a data-driven integrated system that will enable improved responsiveness in manufacturing, leading to more flexible factories of the future [Branke, .et al 2016].

The industrial digital transformation pushed with the vision of adaptability with growth in the medical sector, is what is needed for Personalised Medicine to no longer be considered as much a concept but rather a paradigm towards medical evolution. The development would require extensive adjustments to how the healthcare system is delivered, supply chain is managed, and education delivered in schools. The need for new skills for healthcare professionals, inter-collaboration between interdisciplinary and novel tools or systems for delivery becomes essential to the process. Vicente, A.M, .et al [2020]. With this follows the Digital Enablers provided by the industry 4.0 movement. In the pharmaceutical sector, the use of 3D printing enables 'smart' design in terms of size, dose, appearance, and rate of delivery of a drug to comply with individual needs. Using 3D printing technology, hospital pharmacies and local pharmacies, are likely to see their roles and form of practice change completely. An example would be the produce of precise prescriptions, eliminating the need to stock large quantities of generic medication. [Aquino, R.P. et al [2018].

Individualizing patient treatment is a core objective of the medical field. Reaching this objective has been elusive owing to the complex set of factors contributing to both disease and health; many factors, from genes to proteins, remain unknown in their role in human physiology. Ho, D.et al., [2020].

The study conducted by Ho, D. et al., [2020] highlights key breakthroughs in the development of personalised medicine. They discuss on enabling technology and how its integration with one another help further the goal of developing personalized drugs. They also cover on policies and concerns around the process, recognising 3d printing as well as other digital enablers such as Artificial intelligence, Machine Learning and Big data management system, highlighting their use and potential towards the practicality of precision medication. They also go further covering concerns, criticisms of regulator and healthcare practitioners around the challenges of personalised medicine and 3D printing detailing ethical concerns and timeframe for ideal implementation.

Relevant notes were made in the assessment of Personalised medicine into the health system but, brief detail on larger issues faced were insufficiently mentioned. A study conducted by C.H Le et al 2011 however, present a paper on personalised medical products, their design, and developments. Their presentation emphasised mainly on design and manufacturing of implants, surgical tools, medical devices, orthotics, and prostheses. Technologies, methods, and resources on the development of these personalised medical products are presented with their issues, limitations, and the opportunities they bring. Although the presentation throws emphasis on the specific products or groups of products and applications, they generalise challenges and opportunities for research and development of medical products for Personalized healthcare from which suggestions for further investigation on design and manufacturing methods as well as software and tools for personalised product design and development are made and summarised. Considerations to the development of personalised medicine for tablet manufacturing is not mentioned. However, a layout of key factors and point for solutions around patient data and the design and manufacturing is discussed as presented in Figure 1. The mentioned components in the study pose a similar faith of condition in effectively implementing personalised medicine delivery.

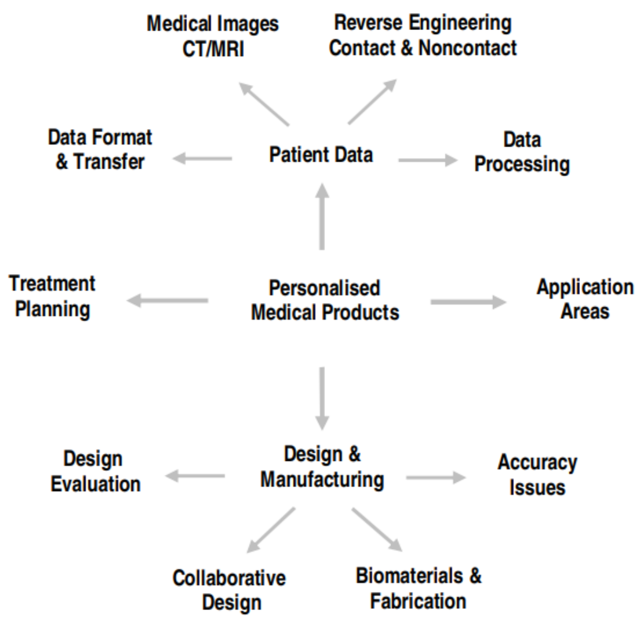


Figure 1. Key Factor in the design and development of Personalised medical products [C.H Le et al, 2011]

2.2. Additive Manufacturing

Additive manufacturing is a well-recognized manufacturing process that involves the construction of three-dimensional objects from computer aided design models or digital 3D model. Its history can be traced back as far as the 1980s when the first 3D printers were created. Ever since then, additive technology has experienced immense evolution, with which new technologies and production processes have been developed, incorporated, and commercialized in many industrial sectors.

Chuck Hull, and American inventor and co-founder of 3D Systems is the man responsible for the invention of Additive manufacturing from the invention of Stereolithography. A process by which light causes chemical monomers and oligomers to cross-link together to form polymers. However, the concept was first presented in 1980 by Dr Hideo Kodama, a Japanese researcher at the Nagoya Municipal Industrial Research Institute, who filed the first AM patent. His idea was to use a container of photopolymer material and expose it to light to create prototypes but was abandoned due to a lack of funding. Shortly after Chucks' invention, Carl Deckard developed Selective laser sintering (SLS). It is a 3d printing process that uses high-powered lasers to bind finely powdered material together to make a solid structure. The 1990s was a decade of rapid growth for additive manufacturing technology due to the influence of change between the second and third industrial revolutions that brought about new advanced technology and it has grown ever since. In 1999, researchers at the Wake Forest Institute for Regenerative Medicine created the first 3D-printed tissue which marked a breakthrough for application of the manufacturing process in the medical field. May, V. [2022], Sharma, N. and Sharma, W [2019].

Additive manufacturing technology are used in various applications across different industries. The automotive and aerospace industries being some of their major consumers and practitioners of this manufacturing process. As part of this industrial revolution within the medical field, 3D printing is predicted to portray a vital role in the production and mass customisation of highly complicated and personalized medical products [Englezos et al., 2023]. There are also new developments within the healthcare sector and consumer goods that have brought about transformation to how products are designed and manufactured thanks to AM. Various studies in go in depth and others an overview into the creative application of 3D printing both designed or proposed by scholars and some already utilised in industry though minuscule.

A study conducted by Sharma, N. and Sharma, W [2019] that delves into the 3D printing industry and recognises the process as an Enabler to the next industrial Revolution. The study runs through the history of the process and summarises in definition the various types of additive manufacturing processes that are widely known and practised, such as Binder Jetting, Powder Bed Fusion, and Directed Energy despotising etc. They also provide a summary of applications in various industries with practiced scenarios. One investigated the use of 3D printing the educational sector where schools were asked to explore innovative ways of using the 3D technology to help teach more complex scientific and mathematical ideas. The examples shown in these reviews the strategic means in which 3D printing forms as a digital enabler to push the mentioned industries towards industrial change but scratches the surface.

A review study written by Vaz, V.M. and Kumar, L (2021) summarizes considerations to why 3D printing technology is a promise to Personalised Medicine. They discuss important and technical details involved beginning from its history. It covers the concept as an adopted solution/process for several healthcare and pharmaceutical challenges. The study then focuses on the developments within the pharmaceutical industry giving a detailed run-through of the 3D printing methods being used as well as technical explanations how. They go further to discuss the possible future application of this technology and how it could be in a clinical setting, where prescriptions could be dispensed based on individual needs. They concluded with various challenges faced by the procedures, noting areas which must be overcome for the success of 3D printing towards personalized medicine. However, and though outside the scope of their aim, the study fails to present a digital strategic ideology of how organisations use 3D

Printing as a business enabler. Despite that the information presented with further research provides enough to logically assume or conclude on the strategic positions taken by the organisations mentioned. The paper concludes on future works and study both proposed by them and in the works by other organisations on the use of 3D printing in the medical and pharma industry. The rich bibliography from this study presents itself a great well for information to be explored.

Over multiple decades, a large variety of 3D printing techniques have been introduced into the medical industry. Figure 4 shows in chronological record of some of the important achievements 3D printing in pharmaceutical and biomedical application [Jamroz et al, 2018]. Several classifications to existing techniques have been put in record by scholars, with the most based on their different deposition system. A study conducted by Jamroz et al classify these methods as seen in Fig 3 based on the Powder solidification, Liquid Solidification and Extrusion based system. On the other hand, a review study from Konta et al, 2017 presented current 3D printing techniques used for medicine manufacture under 3 categories, Printing-Based Inkjet Systems, Nozzle-Based Deposition Systems and Laser-Based Writing System. The study also presents a table of summarised comparison of all techniques, detailing the drug types, polymers, pros & cons of each process. – see Table 1.

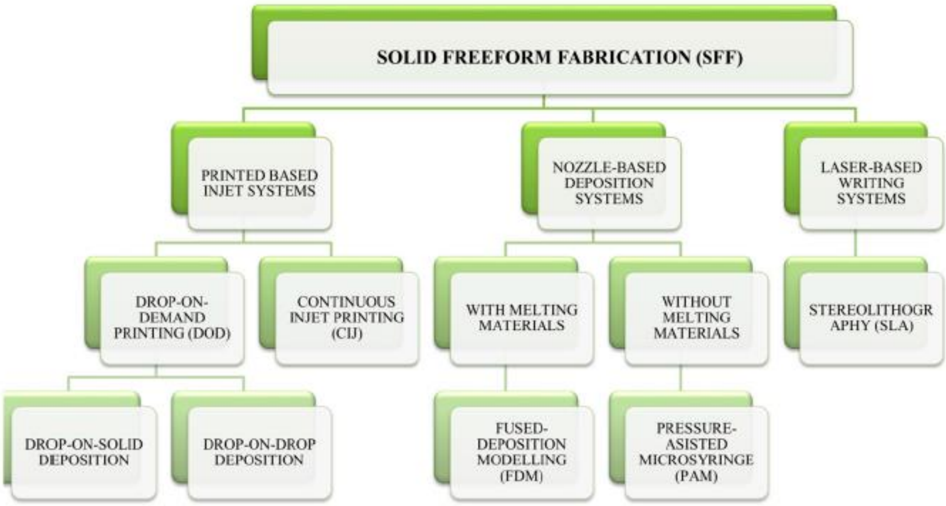


Figure 2. 3D Printing Technologies for Medicine Manufacture [Konta et al, 2017]

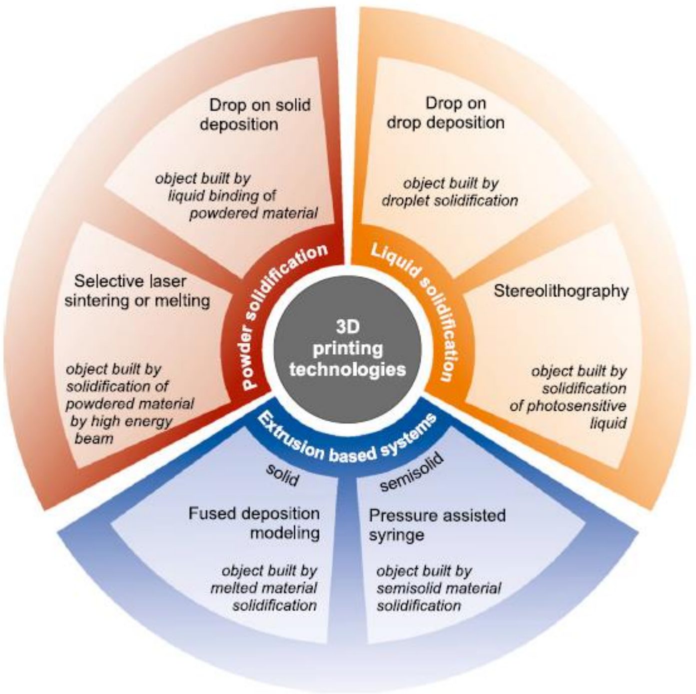


Fig 2 3DP methods applied for drug formulation.

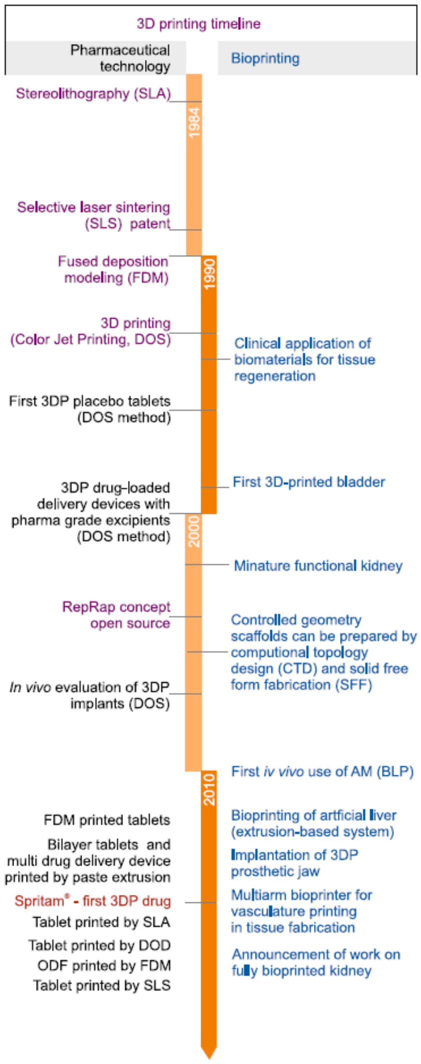


Figure 3 (left). 3D printing methods for drug formulation by classification [Jamroz et al, 2018]

Figure 4 (right). Chronological achievements in 3D printing in pharmaceutical and biomedical applications [Jamroz et al, 2018]

2.2.1. Additive Manufacturing Techniques for Personalised Medicine

2.2.1.1. Printing-based Inkjet Systems

Inkjet printing is the term used to generally describe systems that can digitally control formation and placement of small liquid drops onto a substrate using a pattern-generating device. There are two types of printing-based inkjet systems, and they are Continuous Inkjet printing (CIJ) and Drop-on Demand (DoD) inkjet printing. These are both characterized by the presence of a printer head (i.e., thermal, or piezoelectric) and the need to control both drop formation velocity and fluid viscosity. [Goole, J. and Amighi, K., 2016.]

Continuous Inkjet printing (CIJ) – In this a high-pressure pump directs the liquid ink through a 50-80 micrometre orifice diameter, creating a continuous ink flow. A piezoelectric crystal causes the liquid to flow to break into drops at a specific speed and size and at regular intervals of time. [Goole, J. and Amighi, K., 2016.] [Konta et a, 2017]

Drop-on Demand (DoD) inkjet printing – This technique is divided into two subtypes: drop-on-drop deposition and drop-on solid deposition. Both systems have advantage of using multiple materials and colours since they can print different pieces at the same time, layer by layer and the printing time is reduced. In the drop-on-drop deposition system, the drop interposition produces the different layers of the 3D model. On the contrary, the drop-on-solid deposition, known as "powder bed fusion", is based on the projection of drops directly on the solid material. Selective Laser Sintering (SLS) is another technique produced from this, however instead of using liquid ink it employs a laser to bind the powder particles together. [Goole, J. and Amighi, K., 2016.] [Konta et a, 2017]

2.2.1.2. Nozzle-based Deposition Systems

Nozzle-based deposition systems allow direct writing that uses computer-controlled deposition of ink directly from a nozzle to create a 3D pattern by layer-by-layer with controlled composition and architecture. The systems are further categorised based on material melting and processes without material melting. These processes are: FDM (Fused Deposition Modelling), which uses melted components, and PAM (Pressure-Assisted Micro-syringes), which does not require the use of melted materials. [Goole, J. and Amighi, K., 2016.] [Konta et a, 2017]

Fused Deposition Modelling (FDM) - FDM printing is based on the use of thermoplastic polymers such as polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), or polyvinyl alcohol (PVA). Melted materials (API and polymer mixtures) are stored in rolls arranged in such a way that they pass through an extruder nozzle as the process progresses. The nozzle is above the melting temperature of the material, and therefore the polymer-API mixture melts and deposits, layer by layer, in the form of fine filaments that immediately solidified. [Konta et a, 2017]

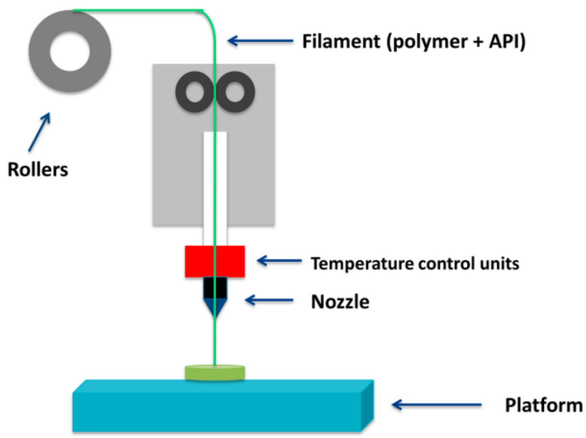


Figure 5. Fused Deposition Modelling Printing System [Konta et al, 2017]

Pressure-Assisted Micro-syringes (PAM) - This technology is based on the use of a syringe extruder that deposits a viscous and semi-liquid material by means of pressurised air piston, layer by layer according to the designed geometry. Viscosity, viscoelasticity, and the apparent elastic limit are the keystone parameters that determine the reproducibility of this technique. It has advantages over other processes, as it has the possibility to work with a continuous flow and at room temperature. However, it also presents disadvantages, like the use of solvents, which are often toxic to health and cause a loss of stability in certain APIs. Its most useful applications are related to tissue printing substitutes or scaffolds of soft tissues, as well as the manufacture of complex drug delivery systems. [Konta et a, 2017]

2.2.1.3. Laser-Based Writing System

It is the basis of the first device invented for the manufacture of three-dimensional products. It was designed by Charles Hull in 1980 and it was called "Stereolithography" (SLA). SLA printers are composed of an ultraviolet light beam, in the form of a laser, which transfers the energy into a liquid photopolymerizable resin. In fact, it is based on the principle of photopolymerization, in which free radicals are released after the interaction between the photo initiator and UV light. [Konta et a, 2017]

Table 1. Comparison of 3D Printing Techniques [Konta et al, 2017]

3D Printer	CIJ	FDM	PAM	SLA
Polymer	Polymer Stabilizer Liquid	Material heat-resistant as melted metals, photo-polymerizable resin and thermoplastic materials	Semi-liquid viscous material	Liquid photopolymer which rapidly solidifies with UV light, as low molecular weight polyacrylate macromers
Polymer Example	Tween 20	PVA, PLA, NYLON, ABS, Polyvinyl chloride	Hydroxypropyl methylcellulose (HPMC), Polyacrylate Methocel® E5	Epoxy Resin Acrylic resin PEGDA (liquid photosensitive resin), Propiophenone 2-hydroxy-2-methyl (initiator)
Drug Type	Slightly soluble in water and organic solvents	Thermoresistant molecule	No specific type	Proteins and Peptides
Drug Example	Folic Acid	Prednisone, Theophylline, 5-ASA	Nifedipine, Glipizide	BSA (Bovine Serum Albumin)
Pros	Works in continuous	Low cost, Good mechanical resistance	Manufacture of Complex drug delivery systems	Smooth surface due to the use of liquid photopolymers, Manufacture of micro-structures
Cons	High energy expenditure and waste generation	Low adequate thermoplastic materials., API degradation due to high temperatures	Use of organic solvents, toxicity, and loss of stability	Lack of FDA approved photosensitive polymers

The application of additive manufacturing in the medical field has been used to produce many FDA-approved medical devices over the past decade, the application of this technology to the production of pharmaceuticals is still in its early stages. However, a monumental breakthrough in the commercial application of the process and as recorded by many scholars was with Spiritam. Spiritam is a prescription medicine orally delivered and used to treat partial-onset seizures in people 4 years of age and older. It is the first approved 3D printed pharmaceutical drug and was developed by Aprecia Pharmaceuticals in 2015 [Parkins, 2022]. The pharmacological efficacy was found to be equivalent with respect to conventional tablets, but with the great improvement that the solubilization time was significantly reduced due to its porous and soluble matrix composition.

Aprecia Pharmaceuticals marked its production using the ZipDose technique, a process based on powder bed fusion, layer-by-layer production system [Aprecia Pharmaceuticals, 2018]. It starts with an initial layering of blended API and all the excipients necessary to produce the matrix tablet. Next the binder liquid is carefully deposited for perfect integration and aggregation between all the successive and identical layers done to produce the final shape of the drug. The result is an oro-dispersible tablet, which dissolves in a few seconds and with little amount of water, consisting of dosage capacity up to 1000 mg of API. This breakthrough highlights the potential of this technology for the development of specialized dosage forms with features not attainable through compression or other conventional manufacturing methods. [Konta et al, 2017]

Research conducted Englezos et al., 2023 also address the technical methods in pharmaceutical production using additive manufacturing methods, but also dive into transitions from experimentation to the consumer and resulting implications for practice and policy. Summary of their study suggests that's Personalised Medicine utilising additive manufacturing or 3D Printers need to be developed within a novel model framework of manufacturing at a community or hospital pharmacy level. As the ability for 3D printing to create PMs is already well established. They suggest for personalised medicine to grow within the framework, five major factors need to come to play to guarantee success. Two Key critical factors mentioned was around the acceptability of doctors and Pharmacist to the process. Understanding to the benefit shown for therapeutic prescriptions, belief in the process, awareness, and change/addition to their education and skills that to allow interaction with them and the technology is mentioned to allow the model to work. Other factors include, economic viability, safety & quality as well as patients' acceptability to the process.

2.3. Digital Strategies

The term strategy is simply defined by most as a plan. In oxford definition it is a plan of action designed to achieve a long-term goal. However, scholars and business analysts tend to define the concept of strategy past this. An article written by [Martin, R.L., 2022] defines strategy as a plan to create value, and in the competitive business world it is defined by some as an integrated set of choices that positions you on the playing field of choice which allows you win. Mintzberg, H., 1987 expands on the concept of strategy and strategic management not being able to be explicitly defined in one manner, rather recognised by multiple definitions. He identifies Strategy as a plan, ploy, pattern, position, and perspective for businesses to view. Changes to the way we work and the adoption of new technology into the industrial market, aids organisations to maintain or gain a competitive edge on the economic market. This enforces the need for a digital strategy in the Digital Era.

In sense of a classic understanding, a strategy is a planned bundle of measures of the company to achieve long-term goals. A bundle of measures consists of many individual measures that are in a consistent relationship to each other. According to the classical understanding, we'd define a digital strategy as an overall vision of a company in the context of digitalization, including the strategic measures to achieve it. This entails concrete, short-, medium- and long-term digitalization goals and initiatives in the context of products, services, and value creation as well as for the organization and culture of a company.

A book written by Ross et al, 2018 touch on what's required of organisations looking to develop a digital strategy. They first describe a digital strategy as a direction that leads the digital initiatives of an organisation and emphasis on choosing what direction to conquest is strongly based on your companies' abilities or known resources. The two digital strategy approach mentioned were: customer engagement strategy and digitized solutions strategy.

2.3.1. Customer Engagement Strategy

In this approach its discussed to focuses on the development of customer loyalty and trust and, in the best cases, passion. Companies making the decision to follow this approach offer continuous, multichannel customer experiences. Quick rapid replies to customer demands, and personalized relationships are also key considerations, built upon deep customer insights. Organisations must recognize the expectations of customers and constantly need to position themselves to identify new opportunities that allow them to connect with their target audience. [Ross et al, 2018]

2.3.2. Digitized Solution Strategy

For the digitized solutions strategy, they discuss the approach as one that transforms what a company sells. Organizations in this model would seek to integrate diversified products and services into solutions, to enhance products and services with information and expertise that help solve customer problems, and to add value throughout the life cycle of products and services. This approach is seen to transform a company's business model by shifting the basis of its revenue stream from transactional sales to sophisticated, value-laden offerings that produce recurring revenue over time. [Ross et al, 2018]

In a study conducted by Lipsmeier, A. et al 2020, they present a process model for developing a digital strategy for manufacturing companies. The paper defines factors a company looking to embrace digital transformation within their organisation must review. These are a digital vision, mission, targets, and policies The study also presents a framework for a digital strategy and how they relate as shown in figure 6 below. The study does present a viable model for digital strategic development that both startups and experienced companies can be a benefactor from but fails to review the process with practical examples.

A study conducted by Correani, A., et al, 2020 presents a model showing how firms can effectively implement a digital strategy by highlighting the core aspects that may concur to define a digital business model. They go about their analysis using three case studies to demonstrate their model and how, it supports companies in implementing their digital transformation strategy. The study provides valuable insight to the direction and core principles of change taken with the examples and how each sector of their business model is centred to involve the new digitized process. They identify key factors such as a clear scope, data source, data platform and customers as some of factors identified to the success of the model's core.

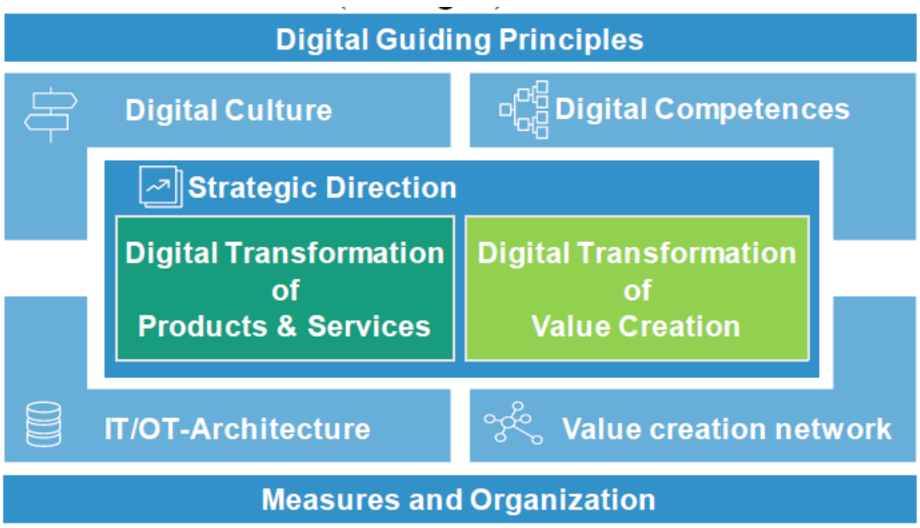


Figure 6. Framework for Digital Strategy [Lipsmeier, A. et al 2020]

3. RESEARCH METHODOLOGY

This chapter sets out to present the methodology used in investigating the research questions corresponding with the known study objectives. Research methodology as described by [Kothari, C.R., 2004] sees the process as a way research problems are scientifically and systematically solved. Research methodologies are a set of defined procedures or techniques used to identify, select, process, and analyse information on a topic of research, presenting readers opportunity to understand and assess the credibility of done study based in the process.

The Healthcare and pharma industry is an area that is not shy of involvement with innovative practices that have insight new industrial practices with transformative means of operation and results. Many new technologies have been smartly introduced with recent trends geared towards the implementation of AI and big data models on various sectors of manufacturing, research, and competitive business fronts. One of the digital enablers introduced and the focus of this study is additive manufacturing aka 3D Printing. Its gained traction not just for its explorative advantages to manufacturing process but into the exploration to expand on rapid prototyping in the industry boosting research and testing. This technology if implemented smartly potentially stands to forever alter the production process of solid dose manufacturing tablets. This research paper general aims to towards formulizing a conceptual digital strategy based on advanced literature for personalised medical practitioners looking to maximise Additive manufacturing tools and techniques as their main digitisation route. However, prior to putting this technology and strategy into practice, it is essential to gain an understanding of the opinions and expectations of professionals working and studying within and around pharmaceutical sector and colleges.

In this thinking, an appropriate research methodology to achieve the study objective was needed and, formulated using a popular research tool recognised as the Research Onion. It's a tool that helps you understand decisions and stances that need to be held to make an appropriate research design and methodology. With this an investigation into an appropriate strategy, philosophical standpoint on the subject, and an approach are devices and considered.

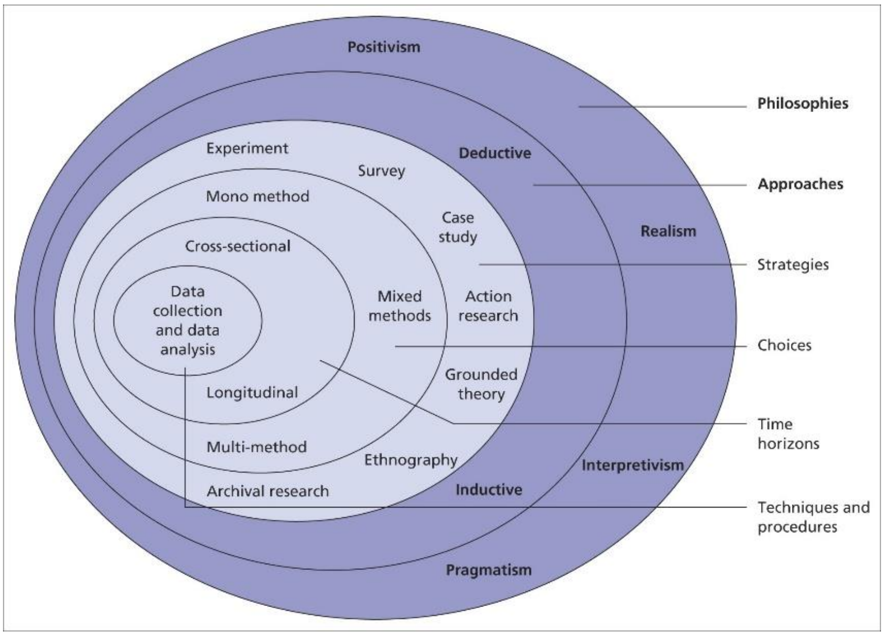


Figure 7. Research Onion [Saunders et al., 2007]

3.1. Research Philosophy

In uncovering layers to the onion, questions and understanding around the objective of this study from a philosophical standpoint had to be made clear on the study. The research philosophy is the basic thinking that sets the foundation of belief, guiding the design and execution of a research. These philosophies are usually discussed in three perspectives, Ontological, Epistemological or Axiology.

Ontology in shorts looks at the understanding of reality. It includes objectivism, constructivism, and pragmatism of which either infers to the authenticity of the information and how one understands its existence.

Epistemology comes from the ideas of positivism, realism and interpretivism and infers to the validity of information required for the research and how one can obtain it.

Axiology teaches you how views and principles affect the collection and evaluation of your research data. It helps one comprehend the influence that public opinion has on the collection and evaluation of research [(Saunders et al., 2007,].

For this study, the philosophy behind the research generally follows both ontology and epistemology, with references to the authenticity and understanding of information being demanded from reliable sources. Hence reference to valid information required for the research with considerations on how it will be obtained is key.

The common philosophical standpoints used by various academic studies are observed to be divided into positivism and interpretivism majorly. Positivism assumes that knowledge is independent of the subject being studied, and interpretivism claims that individual observers have their own perception and understanding of reality. Hence positivist studies are often more scientific and result in testing phenomena and are quantitative in nature, whereas interpretivist studies are often qualitative in nature [15 writers - website]. In this paper, a positivist philosophical view to the study is chosen due to the author independence of the study. No disposition for interference or personal interests within the study led to this choice, with a sole focus on the facts presented.

3.2. Research Approach & Strategy

This study looks to tackle 3 main subject areas and their connection towards a proposed conceptual idea, i.e., Personalised Medicine, Additive Manufacturing and Digital Strategies. The wishful understanding to these topics is subject through literature and expert perspective gathered and sets to elaborate what is required of the research design to achieve set study objectives. The research methodology agreed with based philosophy is created with the idea that the core of results and interpretations to be concluded is based on the quality of data gathered through a meaningful approach.

Based on the research methodology and gathered literature, it is appropriate the study looks to follow an inductive approach for a conclusive theory. Inductive approaches involve constructing ideas from research rather than beginning a project with a theory as a foundation. [Saunders et al., 2007], and with limited knowledge to the ideas of digital strategies in this field research, knowledge from experts' perspective and related literature deem it appropriate.

An agreed justifiable approach strategy for this was the use of a quantitative survey and a systematic literature review. This integrated approach was used in gathering information from a variety of perspectives and from targeted subject matter experts, to draw conclusions about the opinions on their experience, thoughts, and ideas on the utilisation of digital strategies to evolve the application of personalised medicine.

3.3. Data Sourcing, Collection & Analysis

This is the final layer of the research onion and consists of the techniques and procedures used. Data is considered the central piece to any study methodology, and it is what is used to clearly explain the ways and purposes of how the research is conducted. In most studies an expectation of choice between the primary source and secondary source of data are identified. This is also perceived with expectations on whether they are quantitative or qualitative based on how they are sourced.

In this study, paths for both secondary and primary sources of data are used to conduct the research. The major secondary source of data is performed through a systematic literature review of the subject matter. A thorough search of keywords and study of the relevant books, websites, blogs, journals, and various article types from reputable sources were used to generate a wealth of knowledge on the topic.

The large pool of resources allowed for spotting trends and gaps, pushing thoughts on perspective, and formulating new ideas from past research, and finished work advertised by organisations in the development of personalised medication & Additive manufacturing used in drug manufacturing. This gave deep insight to data and information useful for validation and my analysis. It also presented a preparatory guide towards the structure needed for my primary research.

For the selected Primary research, the approach strategy identified the use of a quantitative survey type needed to gather the perspective and expert opinions of the identified industry experts concerned to the subject. Surveys presets a simple process which allows for gathering information in large groups. In addition, questionnaires can effectively collect data while reducing researcher influence and intervention.

A structured questionnaire was prepared using Microsoft Forms designed consisting of 16 close-ended questions with predefined answer choices to collect quantitative data. Certain questions did have open-ended remarks at the bottom to accommodate for extra knowledge from participants and shall be used for analytical consideration or review.

The survey forms were distributed mainly by email but were also shared through other professional social platforms such as LinkedIn, which allowed access to the profile of participants needed to for the study. The criteria using in selecting these study participants were based on:

- Individuals working as Medical Professionals (E.g., Doctors, Nurses, Pharmacists etc.).
- Individuals working as Research Specialist in Academia (E.g., Professor, Research Scientist, Scholar etc.).
- Industry Expert (E.g., R&D Scientist, Regulatory Affairs, QA/QC Specialist, Manufacturing Technicians, Pharmacovigilance, Process Scientist/ Engineers etc.)
- Industry Expert (E.g., Director, Executive, Business Analysts, Operations Officer etc.)

The structure of the questionnaire was simple and made with the intention for increased response rate, making them brief, and simple for participants. It was divided into two sections, first section focused on the demographic information of participants and background information on their knowledge of Personalised medicine and Additive manufacturing. The second section of the questionnaire then delves deeper in context for a further understand of the participants knowledge on its application and considerations to the use of additive manufacturing as a digital device. The survey questions utilised various styles to collect data such as the single and multi-option response, nominal ranking, and Likert type interval scale. All excellent choices in delivering a descriptive comparison of results.

Data analysis is undertaken to make sense out of the respondents' views and opinions of the topic. The process of data analysis began with a cross-examination and cleaning process of of data to ensure its accuracy, consistency, completion, and uniformity. This was all done in a manner to allow proper tabulation for further analysis. A Descriptive approach to the analysis will be done to present relations from participant pool. Opinions formed from analysed findings will form the basis of thinking in research conclusion on PM and AM digital approach. Patterns and trends of results will be relayed with tables, graphs and charts for further analysis and demonstration. Insight information presented by Microsoft forms would also be considered and presented accordingly.

3.4. Ethical Consideration

Ethical implications are well considered within the study as the protection and privacy of participants was taken in high regard. To handle this a simple strategy was devised. Consent and Privacy remains a big concern for most research studies, and to dampen this a kind introduction an explanation of the questionnaire and research purpose was explicitly mentioned in mail and used to begin the form. A consent form began the first section of the questionnaire, with willing participants agreeing to follow through with the survey. Others or unwilling participants who had disagreed to consent were gracefully shown the end of the survey and thanked for their consideration.

The participants were not required to give any personal identifying information such as emails or names which could expose them to risk on the questionnaire. This helped to attain the anonymity of results required, however participants were not allowed to cancel their participation on completion of the survey.

Data Security and Confidentiality procedures to monitor data and ensure security were reviewed and maintained strictly under the project guidelines. All concerns around research data management and storage followed GDPR Guidelines with everything being my sole responsibility till submission. Access to results is limited to the authors personal passworded device (laptop) and form security fall under the data protection services provided with Microsoft forms. All data recorded will later be handed over to the Griffith College as part of a thesis submission. Research Data shall be kept for a duration of 2 years after submission if deemed useful with control on its disposal at the authority and discretion by Griffiths College after handover.

In general, the following informed consent principles were observed: confidentiality of participant information; integrity, care, and fairness in the survey research process; impartiality; participant protection; social responsibility and non-discrimination.

4. FINDING & ANALYSIS

In this chapter of the study an analysis of findings from responses retrieved from the survey questionnaire is reviewed. The insights generated from the data was used to process an understanding on the knowledge, awareness and difficulties faced by Field, Research, and Industry professionals within the Healthcare and Pharmaceutical Business and Operative Industries. The gathered perceptions from experienced minds in the field provided the basis for conclusion of the research study needed in developing a digital strategy for Personalised Medical Delivery utilising additive manufacturing. The survey began with a short introduction of the study followed by a consent message for willing participants to proceed with in Question 1.

4.1. Demographic Data (Questions 2 – 3)

The survey questionnaire began with demographic data questions to effectively understand respondents' current job roles within their respective fields alongside their length of work experience. The questionnaire was distributed to selected participants categorised as Medical Professionals, Research Specialist in Academia & Industry Experts of various roles within the medical and life science field. An estimated total of 80-100 survey questionnaires was shared both electronically and physically, via emails and professional social media site such as LinkedIn and WhatsApp. The physical hands-on approach involved visiting local pharmacies, hospitals, and accessible pharmaceutical company HQ for audiences with target participants, explaining the purpose of study and delivering access to the survey questionnaire on their electronic devices via a printed QR code. During data collection, an improved response rate was achieved after message reminders and second invitations were sent out to participants via emails and text messages. This strategy saw a near immediate reply and rise of notifications for questionnaires completed. A hopeful estimated response of participants per category was 20 minimum for strong viable data. However, total respondent since the date of survey distribution and closed was 34 with 33 consented replies resulting to a survey response rate of 41.25%.

The total 33 willing and responsive participants comprised of 19 Medical Professionals (E.g., Doctors, Nurses, Pharmacists etc.), 11 Industry Expert (E.g., R&D Scientist, Regulatory Affairs, QA/QC Specialist, Manufacturing Technicians, Pharmacovigilance, Process Scientist/ Engineers etc.), 2 Industry Expert (E.g., Director, Executive, Business Analysts, Operations Officer etc.) and 1 Research Specialist in Academia (E.g., Professor, Research Scientist, Scholar etc.). as shown in Fig 8.

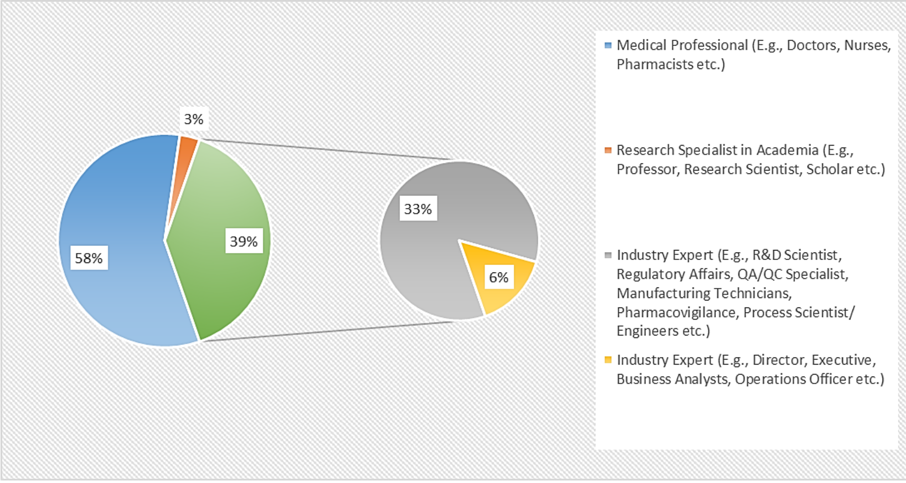


Figure 8. Q2 – Survey demographic distribution by Profession

In respect to the years of experience from respondents, a fair distribution was accumulated, ranging from 1 to over 10 years across the described roles. Out of the 33 respondents who completed the questionnaire, 27% (9) of respondents had a minimum of 1 to 2 years of experience and the majority being 30% (10) of respondents having 3 to 5 years of experience in their current roles. 21% (7 each) of respondents recorded having 6 to 10 and 10 + years of experience respectively.

Table 2. Q3 – Survey Demographic data

Roles/ Professions	**Years of Experience (yrs.)**				**Number of Respondents**	**Response Rate (%)**
	1-2	**3-5**	**6-10**	**10+**		
Medical Professionals (E.g., Doctors, Nurses, Pharmacists)	8	6	4	1	19	95
Research Specialist in Academia (E.g., Professor, Research Scientist, Scholar)	-	1	-	-	1	5
Industry Expert (E.g., R&D Scientist, Regulatory Affairs, QA/QC Specialist, Manufacturing Technicians, Pharmacovigilance, Process Scientist/ Engineers)	1	3	3	4	11	55
Industry Expert (E.g., Director, Executive, Business Analysts, Operations Officer)	-	-	-	2	2	10
Total Survey Response	9	10	7	7	**33**	**41.25%**

4.2. Familiarity & Awareness (Questions 4 – 8)

The response from questions 4 to 8 of the survey were generated to retrieve information on the awareness and familiarity around the concepts of Personalised Medicare and Additive Manufacturing of the study participants. Results of respondents here was interesting and tallied with expectations based on analysed literature. It was apparent from the survey that the distributed base knowledge around the concepts of Personalised Medicare and Additive manufacturing on their own was prevalent amongst respondents. However, when instigated to know if the group were familiar with the cross practice of both concepts it was found lacking.

In the analysis of the participants familiarity on both study concepts, 61% (20) of respondents admitted to knowing about the concept of Personalised Medicare as to the remaining 39% (13) of respondents in Question 4. For Additive Manufacturing, 64% (21) of respondents reported in Queston 5 with being familiar with its concept as to the rest 36% (12) of respondents. – see Figure 9 & 10.

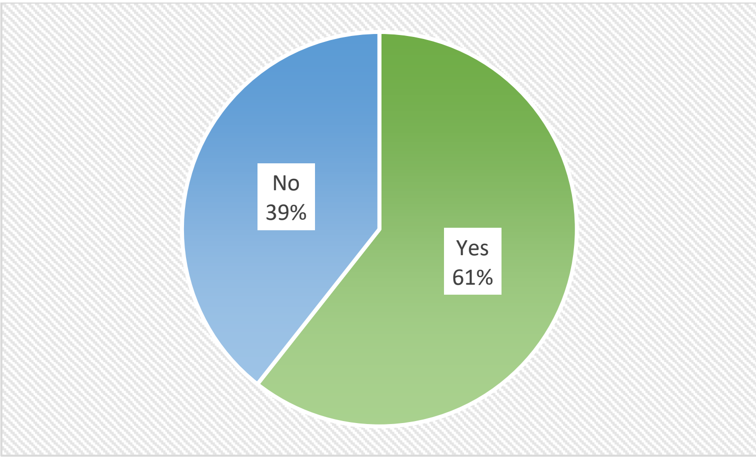


Figure 9. Q4 – Chart on Particpants awareness of PM.

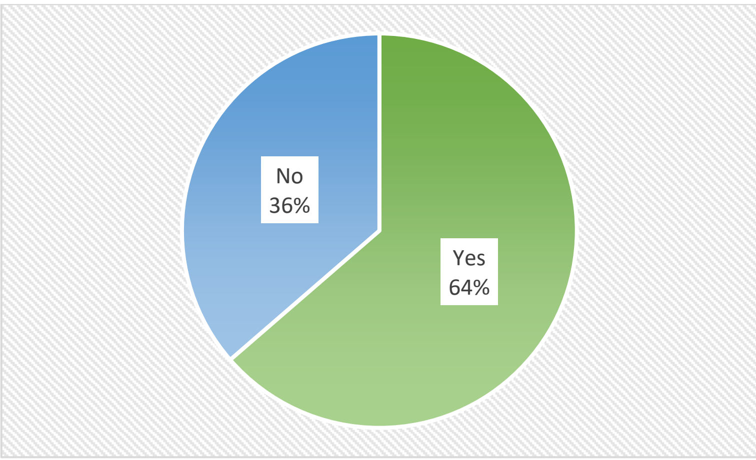


Figure 10. Q5 – Chart on Participants awareness of AM.

Despite this, when asked about participants familiarity with the application of additive manufacturing in personalised Medicare, particularly personalised medicine therapy prior to the survey in Question 6, a whopping 82% (27) of respondents reported unfamiliar with the practice as to the remaining 18% (6) who replied yes. – see Figure 11

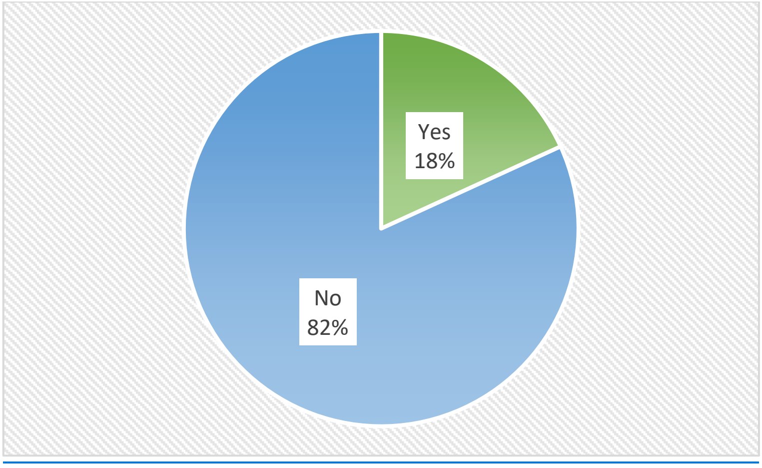


Figure 11. Q6 – Chart on Participants awareness on AM application in PMT prior to survey

Interestingly of the percentage of participants unfamiliar with both personalised medicine therapy and additive manufacturing 83% (5 of 6) of respondent were found to be Medical Professionals (E.g., Doctors, Nurses, Pharmacists) primarily with low work experience from 1-5 years. Only one participant with no prior knowledge of the practice or application of either concepts was found to be an experienced industry expert (E.g., R&D Scientist, Regulatory Affairs etc.) with 10+ years' experience.

To further sample the participants knowledge on the current use of additive manufacturing on personalised medicine therapy, Question 7 presented participants with a ranking system to rate their understanding of the process. An average reported score of 1.64 was retrieved following participants responses.

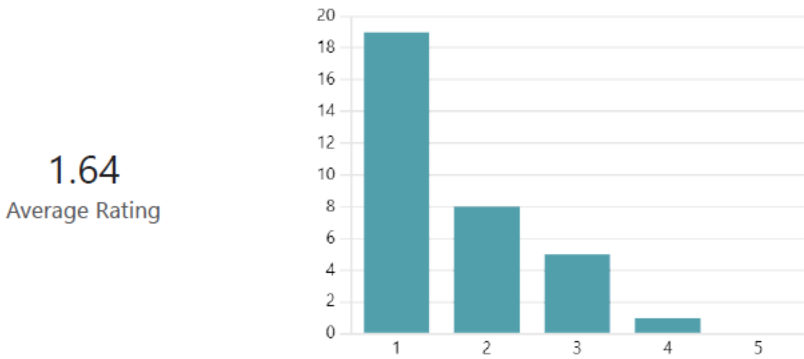


Figure 12.Q7 – Participants ranking on their knowledge of AM used in PM

Question 8 on the other hand presented a multi-choice question type presenting a list of additive manufacturing techniques in study and practice applied towards development of personalised medicine therapies. An open text box for participants to record any known techniques not mentioned in the list was a selected option provided. However, recorded answers from 10 respondents identified their lack of knowledge on any of the listed additive manufacturing technique. The popular response in this section would be the basic 3D printing practice which was selected on 22 counts by respondents. This technique would be more popular for solid manufacturing practice and involve the successive layering of materials to form a three-dimensional object following designs of a digital model. In relation to profession roles of participants 59% (13) of respondents that are medical professionals claim to be familiar with the process. 41% (9) of respondents familiar with the process are Industry Experts. Second popular selected process via the survey results shows 5 respondents familiar with the Ink Jet process. In relation to profession of respondents, the experienced industry experts along with only one of the medical professionals, and the Research specialist claimed responsible to being aware of Ink Jet AM technique. The Bar chart below presents a distribution selection of data collected by the survey on the additive manufacturing techniques used for PM therapy in Figure 13 below.

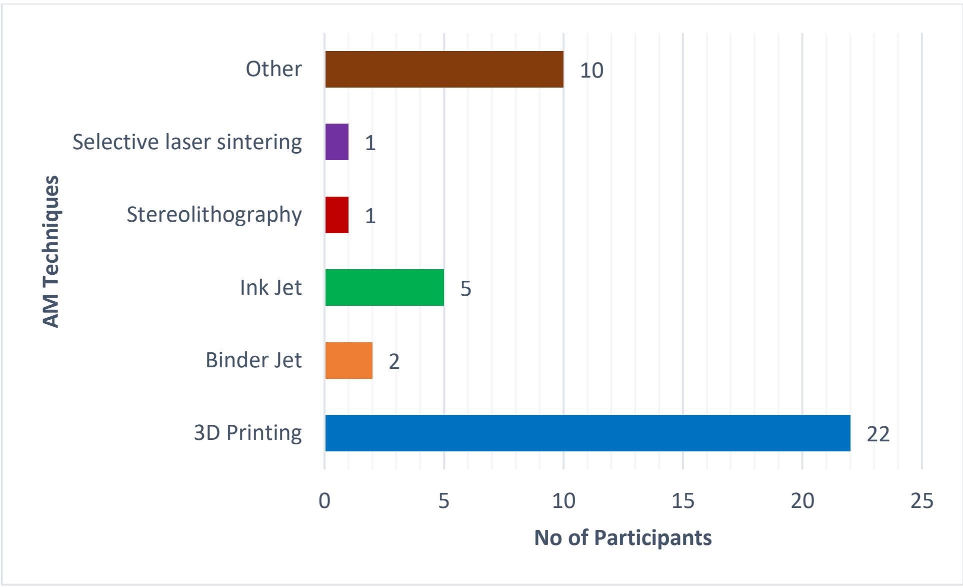


Figure 13. Q8 – AM techniques used for PM. known by participants.

4.3. Experience and Field Impact (Questions 9 – 12)

In this section of the questionnaire, responses from questions generated planned to investigate the exposure of participants to the study concepts based on their roles of practice. It also sought to extract participants perception on the potential impact Additive manufacturing would have on advancing personalised medical therapies on customers as well as influence the medical industry.

Question 9 of the survey searched to extract the level of experience participants had with 3D printed drugs. Author sought to know if participants had personally experienced the manufacture or prescription of any Additive manufactured drug. Results from question 9 validates concerns around the lack of exposure of professionals to the manufacturing of 3D printed personalised drugs. It recorded 94% (31) of respondent attested to not personally witnessing or experiencing this. 6 % (2) of respondent that made up of Industry Experts (E.g., R&D Scientist, Regulatory Affairs etc.) with 10+years of work experience recorded to have witnessed 3D printed personalized medication manufacturing. Despite this, when asked on how Personalised medicine along with the use of additive manufacturing would benefit patients/ consumers in Question 10, a positive turn of result can be observed in the bar chart in Figure 14.

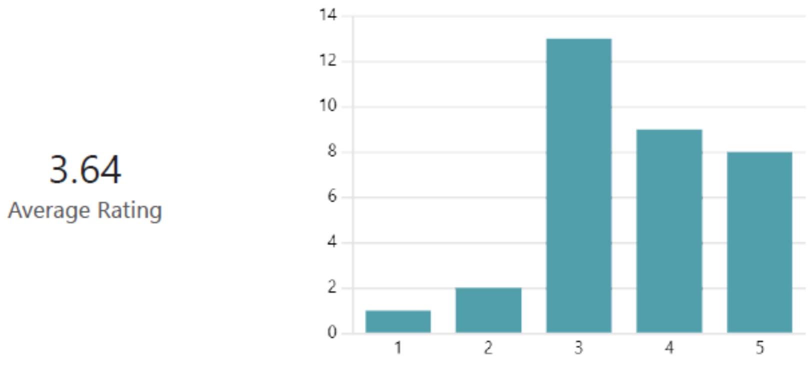


Figure 14. Q10 – Participants ranking on the Usefulness of PM with AM to patients/consumers.

With an average ranking score of 3.64, it's easy to infer industry experts and medical professionals alike remain hopeful to the prospect of these new procedures despite having little personal experience or knowledge of the process.

However, when asked about the effects 3D printed drugs would have in easing the pressures faced by pharmacies and hospitals in Question 11, a near split opinion is shared amongst respondents and interestingly by their roles. 61% (20) of respondents believe it would ease the challenges faced by hospitals with 58% (11) of medical professionals and 69% (9) of total industry experts to share this opinion. However, 39% (13) of respondents believe the opposite.

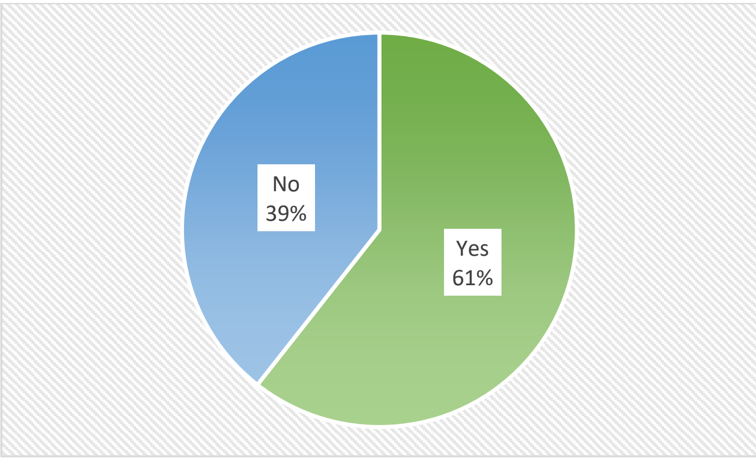
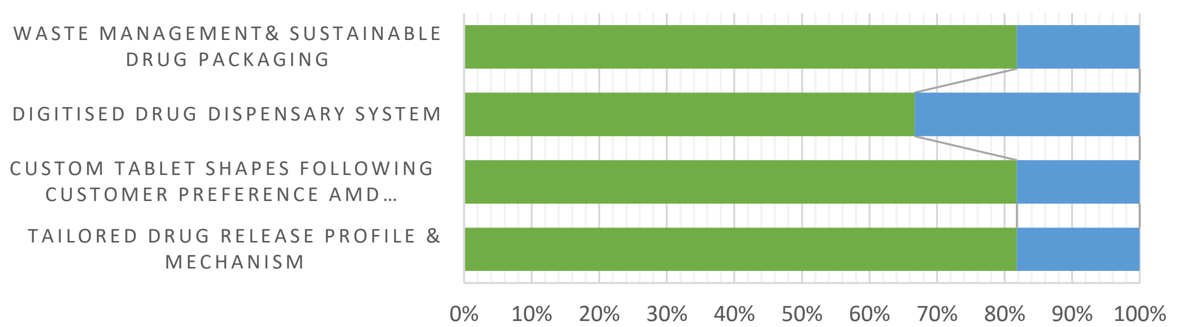


Figure 15.Q11 – Could 3D printed drugs reduce pressure on Pharmacies and Hospitals?

In thoughts to present participants with solutions that challenge issues and drive innovative digital change for the hospitals, pharmacies, and pharmaceutical manufacturing. A Likert type table is presented to participants with a likely to unlikely applications of Additive manufacturing concept for personalised medicine therapies and its manufacturing. Figure 16 presents the results collected from the survey, with the concept idea of an automated digital drug dispensary system utilising chosen 3D printing techniques as the least likely of the other concepts to be possible based on current respondents' perception.



	Tailored Drug release profile & Mechanism	Custom Tablet shapes following customer preference amd prescribed recommendation	Digitised Drug Dispensary system	Waste Management& sustainable drug packaging
Likely	27	27	22	27
Unlikely	6	6	11	6

Figure 16. Q12 – Participants possibility chart for AM on Personalised medicine.

4.4. Challenges & Concerns (Questions 13 – 14)

The digitised concepts listed in question 12 presents significant change to the healthcare, educational and industrial sector of the medical/ life science sector if implemented correctly. In analysing the prospects of change, concerns amongst experts are to be noted for thorough understanding on what to expect. The survey results present insight to the respondents concerns on the revolutionary possibility additive manufacturing possess in the medical field. 67% (22) of participants claimed to not be worried and embrace the possibilities brought about by Additive manufacturing to promote Personalised medicine therapies. However, 15% (5) remain heavily concerned of its broader impact which infers reluctancy to the process, and 18% (6) mildly concerned or unsure with a 'maybe' as their response. – see Figure 17.

Question 14 goes further to list several challenges fairly recognised in literature to help participants identify what the most challenging task towards the full implementation of additive manufacturing in PMT may be. Results show the cost of equipment and materials as perceived participants to be the biggest challenge towards implementation, followed by the limited accessibility to technology - see Figure 18. Other notable challenges contributed via the text box option were, the lack of experience about additive manufacturing in the industry, Logistics, Traceability & Good Manufacturing Practice

(GMP) concerns, Patient Acceptance, Reproducibility, Product cost at low volume and product quality and control.

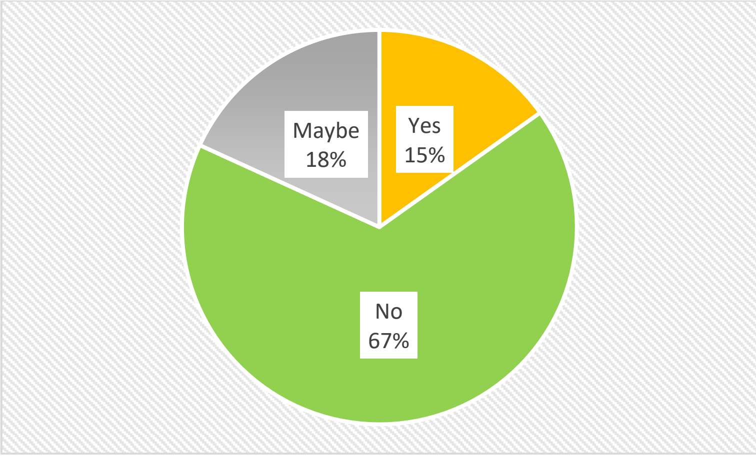


Figure 17. Q13- Are you concerned about AM on PMT in the medical field?

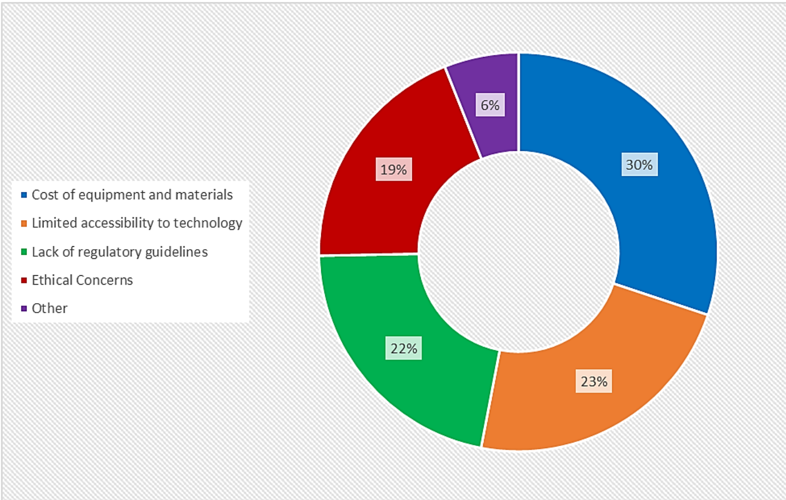


Figure 18. Q14 – What would be the major challenge in implementing AM on PM?

4.5. Digital Impact & Ethics (Questions 15 – 17)

In accessing the digital impact of AM on PMT, Questions 15 and 16 look to investigate participants perception towards the utilisation of necessary digital enablers and strategies to aid the goal of personalised medicine. It also raises concerns and presents insight to the major worry of experts on the digital risks involved with AM and digital enabling tool implementation. 79% (26) of respondents selected in favour of implementing digital technologies and strategies to amplify 3D printing for personalised Medicare while 21% (7) of respondents disagreed - See figure 19.

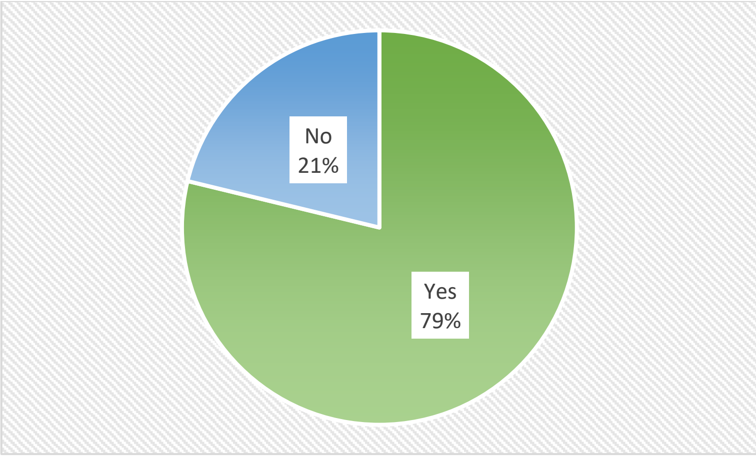


Figure 19. Q15 – Are you in favour of implementing Digital technology & strategy for AM on PM

Risks towards digital revolution have been an area of concern for industry experts and researchers, and the questionnaire highlights some of the social and technical risks involved with the implementation of digital technologies and strategies on PMT. Question 16 as presented in Figure 20 survey results, show several high-class concerns around patient data use & accessibility. Participants responses aid author in identify which risk is regarded of highest concern towards digital technologies. Results show participants are most concerned about patient data security, with the fathomed prospect of personal information being hacked or unethically accessible to dangerous hands. In utilising these digital tools participants also well acknowledge in their selection the fears of patient data being manipulated by companies and government for commercial stints and for targeted or discriminatory bias.

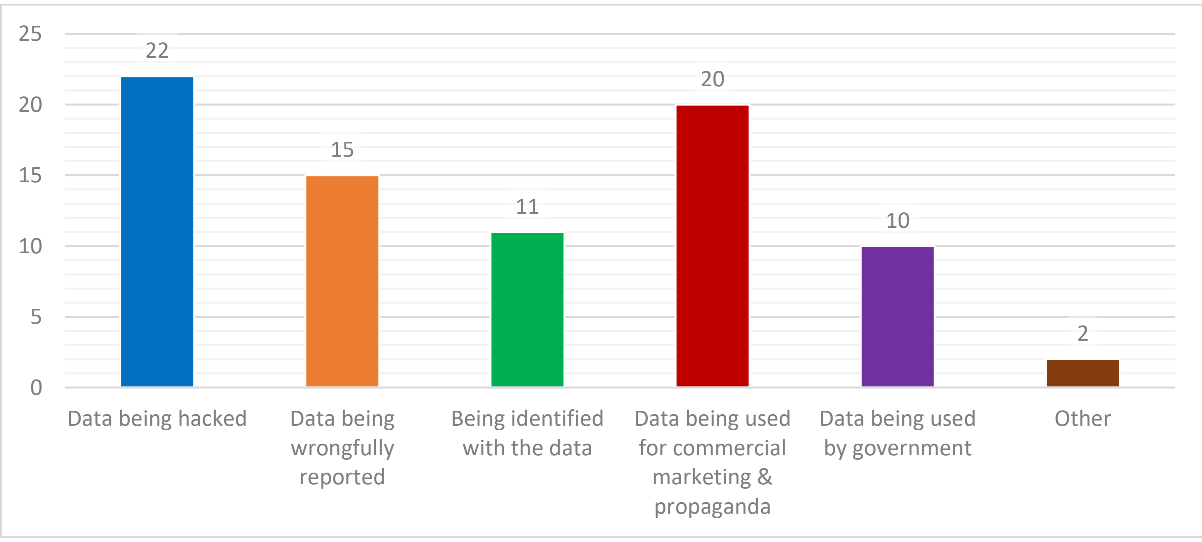


Figure 20. Q16 – Which Digital Risk presents the biggest challenge to digital tech and strategy implementation?

Given the listed concerns around the implementation for digital technologies and strategies, the author seeks to understand based on participants opinions which roles in the industry is regarded as the most appropriate to be involved in developing governing digital and ethical policies needed for AM on PM. Results from the survey as presented in Figure 21 suggest healthcare professionals to be at the forefront of policy making decisions, followed by additive manufacturing experts. These suggestions can be inferred from the need to cover the gaps of knowledge between medical administrators and additive manufacturing processes in the industry. Next role suggested for consideration was the Research and Academic experts. It could be inferred due to the importance of their role within the industry, as AM would lead to a significant change as well as digital revolution that would alter both manufacturing and education system in the field. They could also form the bridge of knowledge between the healthcare professionals and AM experts. Other notable suggestions from participants were medical ethics leaders and digital tech leaders.

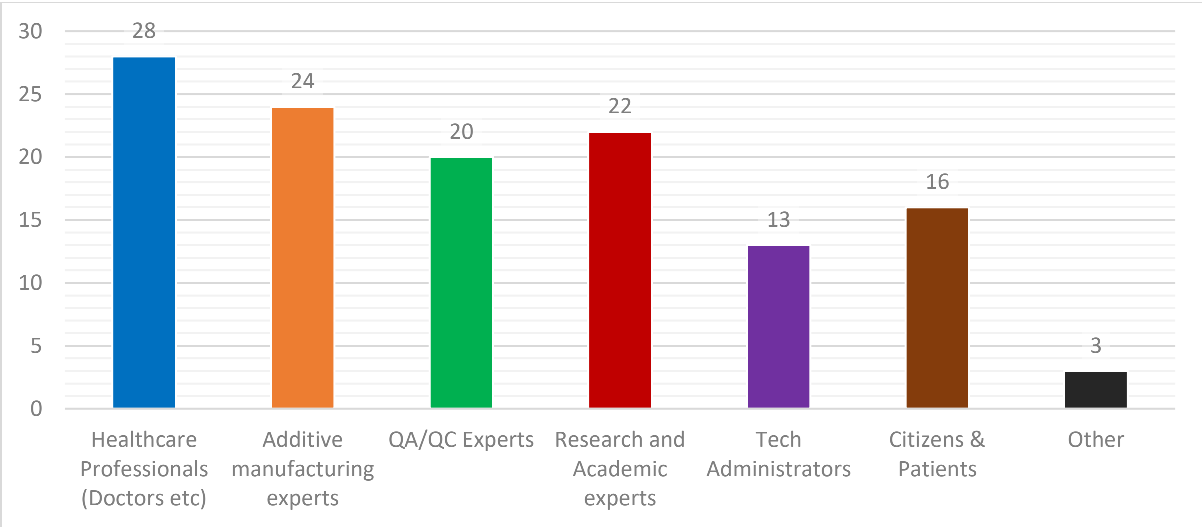


Figure 21. Q17 - Who should be involved in Digital Policies for AM on PM?

5. DISCUSSION & CONCLUSION

Just like many industrial sectors, the pharmaceutical and Healthcare industry are well within a transformative era due to social, commercial and policy changes and trends aimed for improvement. The niche ideology of personalised medicine is a fore practice many organisations look to accomplish within the sector. The possibilities encouraged by new technology and the smart applications of the industry 4.0 digital enablers could turn the practice of personalised medicine from niche to mainstream. Although rapid prototyping has made waved in medical practice for researching and testing medical devices and even drugs, the large application of additive manufacturing techniques in the medical field is still relatively new. It's a field that's gaining interest from researchers, manufacturing companies and regulatory authorities. It is poached as one of the many digital enablers that if applied smartly, could transform the pharmaceutical manufacturing industry, and progress the mass adoption of personalised medicine. The manufacturing of complex dosage forms with customised release profiles, enhanced drug delivery and personalized medicine are some of the possible benefits that could result from the utilization of 3D printing in the pharmaceutical business.

This paper sought to develop an understanding of the digital disruptions faced within the industry and review a path for a conceptual digital strategy that would progress the need for additive manufacturing techniques to advance personalised medicine. The ideology was faced with an initial review of key literature to the practice of personalized medicine and additive manufacturing. This was followed by a comprehensive closed-ended questionnaire to extract valuable insights of industry and research experts on the subject.

On initial review of literature, studies make the clear identification of the public awareness on additive manufacturing especially on personalised Medicare to be medium to low amongst the industry experts. The study reviewed from Englezos et al., 2023 shows this with presented results of a conducted survey resulting with 53.2% of participating pharmacists saying they were aware of the general concept of 3D printing but less of 22.4%, revealing they were unaware of its use in the pharmaceutical industry. In comparison with studies from this paper a similar result can be viewed with 64% of participants ranged from doctors, pharmacists, medical researchers, and regulators admitting being knowledgeable on the general concept of Additive manufacturing but 82% of them unaware of its practise on personalised medicine manufacture. The results of the authors survey also revealed that despite the decent populous of respondent being familiar with the concepts, that a lack of understanding of additive manufacturing techniques applied in drug manufacturing is low. Nevertheless, the survey conveyed various applications of the manufacturing process towards personalised medicine application for product and as a model for digitised operations. Survey conveyed optimistic result with participants decision towards practical listed outcomes of 3D printed drug manufacturing for personalised medicine and also welcome the invitation of digital strategies and with new technology by companies to help advance the process.

Upon review of literature, key factors were cross examined into generating a simple 4 step process for companies looking to develop a digital strategy which utilises additive manufacturing capabilities.

1. **Business Model assessment**: whether for startup or an established firm a clear assessment of a company's business model is the first step to examine their business capabilities and for some to identify what position, activity and trade-offs needs to be made to execute this change. A great tool to help with this would be a business model canvas. Based on the tool design companies would be able to visually breakdown and identify key factors of their business such as their Key partners, Activities, Value proposition, resources, Customer relationship, channels and even cost structure
2. **Digital direction**: This infers to the strategic approach an organization takes to embrace digital technologies and how they are integrated into all aspects of their business, including operations, customer interactions, and more. As discussed in chapter 2, two clear routes could be utilised when considering Additive manufacturing technology as the major digital enabler. The direction decided stakes claim to what's required for the next step and how AM could be implemented towards PM progress. Following a customer-engaged approach, promoting personalised medicine to customers will require loyalty, transparency and trust that would achieve via the customization potential presented by 3DP. In the case of a Digitized solution strategy, 3DP would present a remodel of the manufacturing process depending on how it is utilised. A concept idea follows licensed pharmacies utilizing 3DP to digitally dispense prescriptions for customers into reusable/recyclable bottles or packs supervised by a licensed pharmacist with 3DP operative training.
3. **Digital Vision –** this is a declaration of digital aspirations an organisation would need based on their preferred digital approach. This is largely supported by a mission statement explaining the reasons for the direction taken by the company.
4. **Digital Policies -** represent the central values and principles of conduct regarding digital leadership, digital innovation, data use, data and IT security and fundamental organizational changes.

To conclude,

> *How would a digital strategy help overcome challenges presented by personalised medicine and additive manufacturing?*

Evidently, finding shown from primary research suggest the lack awareness amongst industry experts on the use of additive manufacturing for personalised medicine. It would leave to suggest this as one of the number challenges around personalised Medicare or additive manufacturing implementation. Although it’s a green area and not widely popular in the field, a clear digital strategy shown with intent would suggests a direction towards advertising what features additive manufacturing alongside other digital enablers such as AI and blockchain model would help towards up scaling the practicality and proving commercial viability.

> *What ethical and regulatory considerations must be considered when using additive manufacturing in personalised medicine?*

In this case, suggestion from primary and secondary research highlight concerns from experts on the data security and a gap of knowledge between additive manufacturing, medical and data experts. A clear digital strategy would provide and organisation with a digital identity governed by diligent digital policies. This would challenge the ethical concern this providing clear guidelines towards the protection and use of data to maintain quality, protect clients and avoid the risk of manipulation commercially or by government.

3D printing for personalized medicine is an attractive concept for pharmaceutical companies carrying the added possibilities for complex dosage forms, tailored release profiles and digitisation for a better drug administrative process. For future works, a study to improve awareness of the process could be reviewed and a model Design for digital framework and digital business model shaped around utilising 3D printing in personalised medicine manufacture, providing a clear implementation plan.

On the other hand, there have been limitations towards the research. The study was conducted among the research and industry experts mainly in Ireland limiting the range of opinions applicable for Irish medical system. However, the overall study was to analyse a generalised idea that should be suitable for any organisation within the sector looking to adopt a digital strategy to use. Despite the attempt to contact as many people to increase the sample pool of participants, a poor respondent rate can be seen suggesting better outcome of results could be attained if given more time for research.

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APPENDIX

Survey Questionnaire

UTILISING DIGITAL STRATEGIES TO IMPROVE PERSONALISED MEDICINE DELIVERY THROUGH 3D PRINTING

Dear Participant,
I am a master's student at Griffith College Dublin studying for an M.Sc. in Digital Transformation (Life Science) and I am conducting a study to uncover a proposed digital strategy to enhance Personalized Medicare delivery, utilizing Additive Manufacturing. The research looks to identify challenges faced with precision medicine, measure the potential of Additive manufacturing, and determine a strategic solution for organizations providing precision Medicare services.

I am happy to invite you to take part in this research study and grateful if you can complete this questionnaire. Thank you so much!

* Required

1. CONSENT *

By ticking the box below, you decide to agree or disagree to participate in this research voluntarily and understand the nature of the project. Responses you supply are anonymous and will not be possible to be subsequently withdrawn. There will be no personal identifying information attached to your answers. By consenting to participate in this research, you are not waiving any of your legal rights. *

◯ I agree.

◯ I disagree.

INTRODUCTION

As the world continues to evolve and adapt by adopting new materials, technology and practices, the goal around the life science and medical sector remains unchanged. The provision of health care services to prevent problems and maintain the health of patients. With this the wider individualization of patient treatment remains a core objective and a direction challenged by themedical field.

Tailored prevention and care for individuals describes the main aim of personalized medicine. In this way, people can improve their health or avoid chronic diseases, using information on their genes and lifestyle. However, factors around this goal provide contributing challenges, from better understanding of disease mechanisms, limitation with technology and social and safety re- views or concerns.

In this survey I would like to know about your views towards the idea of Personalized medicine delivery; 3D Printing; Digital Enablers & Strategies; governance of the research and introduction in health care.

2. Which of this best describes your current role of profession? *

- ◯ Medical Professional (E.g., Doctors, Nurses, Pharmacists etc.)
- ◯ Research Specialist in Academia (E.g., Professor, Research Scientist, Scholar etc.)
- ◯ Industry Expert (E.g., R&D Scientist, Regulatory Affairs, QA/QC Specialist, Manufacturing Technicians, Pharmacovigilance, Process Scientist/ Engineers etc.)
- ◯ Industry Expert (E.g., Director, Executive, Business Analysts, Operations Officer etc

3. Please select the option that best represents your years of experience in the mentioned role: *

- ◯ 1 to 2 years
- ◯ 3 to 5 years
- ◯ 6 to 10 years
- ◯ 10 years+

4. Are you familiar with the concept of Personalized Medicare? *

◯ Yes

◯ No

5. Are you familiar with the concept of Additive Manufacturing (3D Printing)? *

◯ Yes

◯ No

6. Had you heard about the application of Additive manufacturing in personalized medicine therapy prior to this survey? *

◯ Yes

◯ No

Section 2

In this section, questions on your knowledge, views, and perspective on governance of additive manufacturing process using for personalized Medicare therapies would be asked.

7. How would you rate your knowledge about the current use of additive manufacturing in personalized medicine therapy? *

1	2	3	4	5

Poor Good

8. Are you aware of any specific additive manufacturing techniques used in personalized medicine therapy? (Select all that apply) *

- [ ] 3D printing
- [ ] Binder Jet
- [ ] Ink Jet
- [ ] Stereolithography
- [ ] Selective laser sintering
- [ ] Other.

9. Have you personally witnessed or experienced the manufacture and use of 3D printed medication? *

- ◯ Yes
- ◯ No

10. How do you think Precision Medicine along with Additive Manufacturing will benefit patients/consumers? *

Not Helpful ☆ ☆ ☆ ☆ ☆ Very Helpful

11. Do you think on demand 3D printed drugs would ease pressure faced by pharmacies and hospitals? *

◯ Yes

◯ No

12. Which do you believe to be the likely outcome of the use of 3D printing for precision medicine delivery? *

	Likely	**Unlikely**
Tailored Drug release profile & Mechanism	◯	◯
Custom Tablet shapes following customer preference and prescribed recommendations.	◯	◯
Digitized Drug Dispensary system	◯	◯
Waste management & Sustainable drug packaging	◯	◯

13. Are you worried about how additive manufacturing on personalized medicine therapy could revolutionize the field? *

- ◯ Yes
- ◯ No
- ◯ Maybe

14. What do you perceive as the major challenges in implementing additive manufacturing in personalized medicine therapy? (Select all that apply) *

- ☐ Cost of equipment and materials
- ☐ Limited accessibility to technology
- ☐ Lack of regulatory guidelines
- ☐ Ethical Concerns
- ☐ Other

15. Are you in favor of implementing Digital technologies and strategies such as AI, Big Data, Machine learning models and digital platforms? etc., to amplify 3D printing for Precision Medicare? *

- ◯ Yes
- ◯ No

16. Which of these digital risks do you perceive the biggest challenge to implementing digital technologies and strategies for Precision Medicare? *

- [ ] Data being hacked.
- [ ] Data being wrongfully reported
- [ ] Being identified with the data.
- [ ] Data being used for commercial marketing & propaganda
- [ ] Data being used by government.
- [ ] Other

17. In your opinion, who should be involved in the making of policies around the use of digital strategies for additive manufacturing for precision Medicare? *

- [ ] Healthcare Professionals (Doctors etc)
- [ ] Additive manufacturing experts
- [ ] QA/QC Experts
- [ ] Research and Academic experts
- [ ] Tech Administrators
- [ ] Citizens & Patients
- [ ] Other