IJPSR (2021), Volume 12, Issue 12 (Review Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 12 September 2021; received in revised form, 09 November 2021; accepted, 17 November 2021; published 01 December 2021

SYNCHRONIZING CLINICAL DEVELOPMENT STRATEGY WITH TECHNOLOGY INNOVATIONS IN MEDICAL DEVICES

Manish Narang [*1,2], Ramanpreet Walia [2], Upendra Kaul [3] and Krishnakutty Sudhir [4]

Medical Affairs-Asia Pacific & Japan, Department of Medical Affairs [1], Abbott Vascular, New Delhi - 110025, India.
Amity Institute of Pharmaceutical Sciences, Amity University [2], Noida - 201301, Uttar Pradesh, India.
Department of Cardiology [3], Batra Hospital and Research Centre, New Delhi -110062, Delhi, India.
Department of Medical Affairs [4], Abbott Vascular, Santa Clara, CA, USA.

Keywords:

Medical device, Technology innovation, Clinical development strategy, Artificial intelligence, Postmarketing plan, Machine learning, Clinical research

Correspondence to Author:
Manish Narang

Director Medical Affairs, Department of Medical Affairs, Abbott Vascular, New Delhi, India & Ph. D Scholar Amity Institute of Pharmaceutical Sciences, Amity University, Noida - 201301, Uttar Pradesh, India.

E-mail: manish.narang@abbott.com

ABSTRACT: The earliest anecdotes of 'medical device' dates back thousands of years. In 7000 BC, Neolithics used flint-tipped drills and bowstrings for dentistry. However, regulation of medical devices has only happened recently. Modern medical devices are used for the diagnosis, cure, mitigation, treatment, or prevention of disease. This industry is one of the most dynamic, disruptive, and fastest-growing among all segments in healthcare. However, there are challenges. The transition from innovation to patient care and eventually financial success has proven to be the Achilles hill for most organizations attempting to create a niche within the industry. There has been a multitude of problems to deal with. Financial, operational, technological, and regulatory issues have been plaguing the industry for years. Thankfully, with the advent of new-age technologies like artificial intelligence and machine learning, we are witnessing a paradigm shift in this space. In this review article, we delve deep into the history, evolution, and challenges in the medical devices space. We also look at the emerging technologies that are shaping the future. Clinical development strategies for medical device development have to be fully integrated into the initial stages of technology innovation. We provide a detailed roadmap to this effect. We elucidate the synchronization of innovation and clinical development across all stages of product development and commercialization. Lastly, we recommend critical facets of the post-marketing plan that need to be implemented for the financial viability of devices that leaves behind a lasting legacy for its clinical application.

INTRODUCTION:

The Genesis of Medical Device Industry: Medical devices go a long back into human history. The usage of devices for medical use by ancient civilizations dates back to 2000 to 5000 years.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.12(12).6281-89

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.12(12).6281-89

Tools such as forceps, knives, scalpels, lancets, needles and knives were used for several medical procedures. Documented evidence of use of scalpels for incisions, needles for punctures, hooks for holding up blood vessels and skin, drills for removing parts of the skull to access the brain, forceps to grasp or position tissues, immobilize blood flow and hold the skin together while adding or removing stitches, are found in medical anecdotes, pictures, paintings, and other historical archives. Early procedures included tracheotomy, amputations, bloodletting, cataract surgery, bone surgeries, removal of bladder stones, trepanation,

organ removal, *etc*. The earliest instruments used for medical procedures were generally made of stone, flint, or obsidian. Later, metals like silver, gold, and bronze came into medical use. The pre-modern era is generally considered to be from about the 1st century CE to the 17th century. The majority of medical procedures carried out during this era either involved the treatment of injured soldiers or addressing the ailments of rich. With increasing focus, recognition, and structuring of scientific methods in the 17th century, medical devices became more prevalent. However, they were manufactured by doctors or small companies and sold directly to the public, with no regulatory standards to monitor safety or effectiveness.

The 19thcentury was a path-breaking era for medical devices. In 1867, Joseph Lister published his "Antiseptic Principle of the Practice of Surgery", which is considered to be one of the most seminal and pivotal moments in medical science. This ultimately leads to cleaner operating theatres, more successful outcomes, and higher survival rates of patients. Devices such as the stethoscope, the hypodermic syringe, the ophthalmoscope, the electrocardiogram, hearing aids, the kymograph and nitrous oxide as an anesthetic were developed and brought to market. Hospitals and universities slowly started to drive the industry. With the rapid progress in medical, biological, and chemical sciences, medical devices started to play a major role in the diagnosis and treatment of diseases. Today, the medical devices industry is intertwined with human well-being [1, 2, 3, 4, 5, 6].

Definition: The wide range of items that can be considered medical devices makes it difficult to define the medical device industry and estimate its size. Defined broadly, medical devices are items that are used for the diagnosis, cure, mitigation, treatment or prevention of disease. Unlike pharmacological agents, they are usually not absorbed or metabolized by the human body. The European Union (EU) classes medical devices in Article 1 of Council Directive 93/42/EEC, as any instrument, apparatus, appliance, software, material, or another article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
- The investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

United States Food and Drug Administration (USFDA) Definition Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act defines a device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or another similar or related article, including a part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o).

The medical device industry is thus an important component of the larger health care system and plays an essential role by developing new medical

technologies that can improve the ability to diagnose and treat illnesses [7, 8, 9, 10, 11, 12].

The Modern Medical Device Timeline: Innovations in medical and biological engineering have witnessed a rapid progression in the last seven decades. Here is a timeline of the important milestones:

a) 1950s and earlier

- Artificial Kidney
- X-ray
- Electrocardiogram
- Cardiac Pacemaker
- Cardiopulmonary bypass
- Antibiotic Production technology
- Defibrillator

b) 1960s

- Heart valve replacement
- Intraocular lens
- Ultrasound
- Vascular grafts
- Blood analysis and processing

c) 1970s

- Computer assisted tomography
- Artificial hip and knee replacements
- Balloon catheter
- Endoscopy
- Biological plant food engineering

d) 1980s

- Magnetic resonance imaging
- Laser surgery
- Vascular grafts
- Recombinant therapeutics

e) Present Day

- Genomic sequencing and microarrays
- Positron Emission tomography
- Image-guided surgery

The Market: The global medical device market is worth over US$250 billion each year. Forbes calls it a "disruptive" market of US$410 billion through 2023. 40% of the market is controlled by the United States. Europe makes up a further 25% of this global market share, Japan 15%, and the rest of the world comprises the final 20% of the market. The European market is led by Germany, followed by Italy, France, and the United Kingdom. Recent studies by the Congressional Research Service (CRS), BMI Research, and the Advanced Medical Technology Association (AdvaMed) have estimated that total U.S. spending on medical devices was $119 billion in 2011, $125 billion in 2013, and $172 billion in 2013, respectively. These estimates indicate that medical devices account for roughly 4 to 6% of total U.S. healthcare spending [13, 14].

Challenges in Medical Device Industry from Innovation to Patient Care and Profitability: With all the developments in the medical devices industry, the journey has been far from being smooth. There is a trend to make incremental modifications of existing products, punctuated occasionally by an innovation that offers a significantly new mechanism of action, design, or risk profile. Due to this need for frequently upgrading or modifying existing devices, the life cycles for individual products have often turned out to be relatively short compared to prescription drugs. According to industry reports, medical devices are replaced by a newer version every 18 to 24 months.

The shorter life cycle means that the time frame available for return on investment towards research and development is also shorter. This is precisely why medical devices have typically been not as profitable as blockbuster prescription drugs, barring a few breakthrough innovations. There are reasons for incremental improvements rather than substantial leaps or dramatic new developments. The medical device industry had to cope up with some of the following issues:

- Lack of aggressive development schedules
- High cost of product design and development
- Production prototyping & scale
- Need for complex certifications & documentations
- Quality control
- Clarity on regulations

- Device inability to keep pace with changing requirements
- Marketing strategy for new product launches
- Product security and high recall rates

Therefore, transitioning a medical device from a laboratory concept to a physical product is not a simple, straightforward, and linear process. It is complex, dynamic, and influenced by various social, financial, regulatory, and technical factors. It is quite evident that unforeseen challenges can derail the process when innovators and manufacturers do not take a holistic view of the product development cycle from the outset. Just because a new idea works from a scientific or clinical perspective, it doesn't necessarily lead to successful product development and subsequent market acceptance.

The Changing Paradigm: The 21st-century advancements in digital, data, and biomedical technologies offer exciting potential for medical device innovation. From telemedicine to artificial intelligence, robotic surgery, and 3D printing, technology is revolutionizing this industry. In this ongoing COVID-19 pandemic, augmented reality (AR), virtual reality (VR), telemedicine, and artificial intelligence (AI) based solutions have gained traction. While the far-reaching effects of COVID-19 have introduced the world to a new normal, the greatest impact has been in healthcare. In the long term, it has forever shaped the future of healthcare delivery. While it's immediate effect has been on medical technology, with a focus on digital devices and a shift toward a more collaborative product development process. For example, the National Healthcare System (NHS) in the United Kingdom has developed a brain stimulation device available from the pharmacy via prescription. People suffering from mental health illnesses, particularly as a fallout of once in a millennium pandemic like this, have reduced activity in the left frontal lobe, which controls decision-making, personality, and emotional expression. The flow headset is a wearable device that can be attached to the head with the help of electrodes and gives electrical stimulation to that part of the cerebrum. COVID-19 ushered in a new era for telehealth and remote monitoring. Globally, telehealth services were made easier to implement and access during the pandemic, triggering a huge surge in the use of the technology. The growing trend toward digital technologies was already well on its way before COVID-19. Still, there have been dramatic changes over the past year in the areas of telehealth, teleradiology, telepathology, and other remote workflows. Today, emerging medical device technologies are driven by the internet of things (IoT) equipped with wireless communication technologies such as Bluetooth and internet connectivity to facilitate communication. Interconnectivity between these tools and equipment with cloud-based platforms that capture, store, and analyze patient data and health information is the new horizon in medical devices. The advent of these technologies will enable remote patient monitoring, tracking of previous medical prescriptions and patient locations, monitoring patient progress, and providing access to caregivers [15, 16, 17].

The Disease Burden Paradox: At a time when the human race is at its zenith in terms of technological prowess, the same hasn't quite translated to human disease burden. To illustrate, let us look at WHO data. 55.9 million people died in 2017. The world population lost 1.65 billion years of potential life due to premature death in that year. Disease and disability meant that an additional 853 million years of healthy life years were lost. More than 60%of the burden of disease resulted from non-communicable diseases (NCDs), with 28% from communicable, maternal, neonatal, and nutritional diseases and just over 10% from injuries. Cardiovascular diseases accounted for 15% of the total, followed by cancers (9%); neonatal disorders (7%); musculoskeletal disorders (6%); and mental and substance use disorders (5%). Over the years, mortality and morbidity rates have come down. But at the same time, the population explosion has meant that we haven't been able to tackle health issues as we should have.

Wealth & prosperity hasn't quite been synonymous with supreme health. It is time to contemplate. If we can make a driverless car, then we should be able to normalize blood sugar. A doctor should be able to evaluate a patient's heart rate from anywhere. Smart devices should lead to smart care for patients sitting at the comfort of their smart homes [18].

What needs to be done: Cardiovascular diseases, as evident from the WHO data, can possibly be impacted the most. Smart, sensor-based wearable or implantable measurement units to measure ECG, HR, HRV, Spo2, pulse rate, BP, and other vitals, which can store and transmit data wirelessly, is looked upon as a game-changer. While multiple app-based wearable devices have come into use, they are more of a monitoring device and are used by the section of society where disease burden could possibly be at the lowest. In order to make next-generation medical devices reach a sizeable chunk of the global population and particularly the population at risk, fundamental changes in the product development cycle need to be brought in. Integrated approaches connecting the entire stakeholder with patients at the center is the need of the hour. Having a clearly defined, efficient process for requirements planning is extremely crucial in today's highly competitive medical device industry. Following are some of the criteria that need to be fulfilled for medical devices to become 'smart'.

- Should enable the delivery of appropriate therapy at appropriate time and place and for appropriate patient
- Innovation in technology for more accurate diagnosis & therapy
- Effective and efficient communication amongst stakeholders
- Access to patient data (from anywhere)
- Right person for the right job
- Improved access to 'needy' patients

Product Development: The journey from discovery or innovation to market is a bit different for devices as compared to their drugs counterpart. **Fig. 1A** provides a comparison. The typical phases of medical device development have been depicted in **Fig. 1B.**

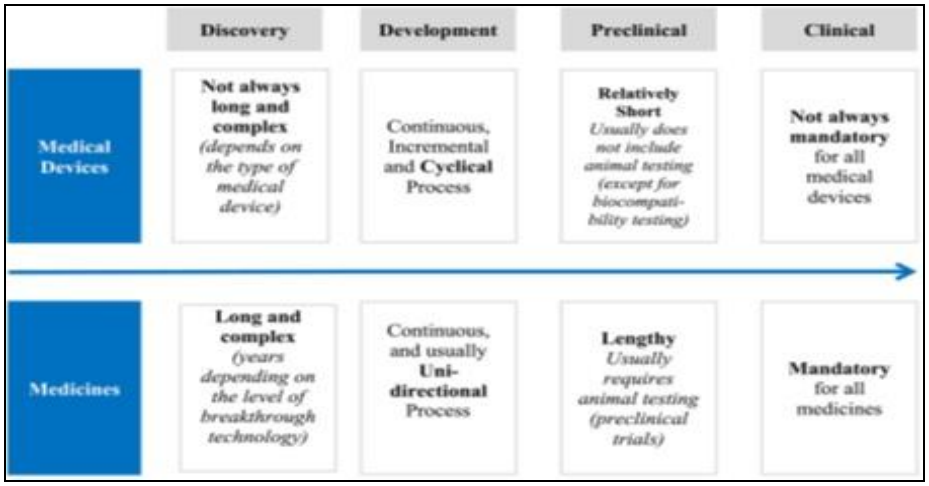

FIG. 1A: COMPARISON OF DEVELOPMENT CYCLE OF MEDICAL DEVICES *VS* MEDICINES

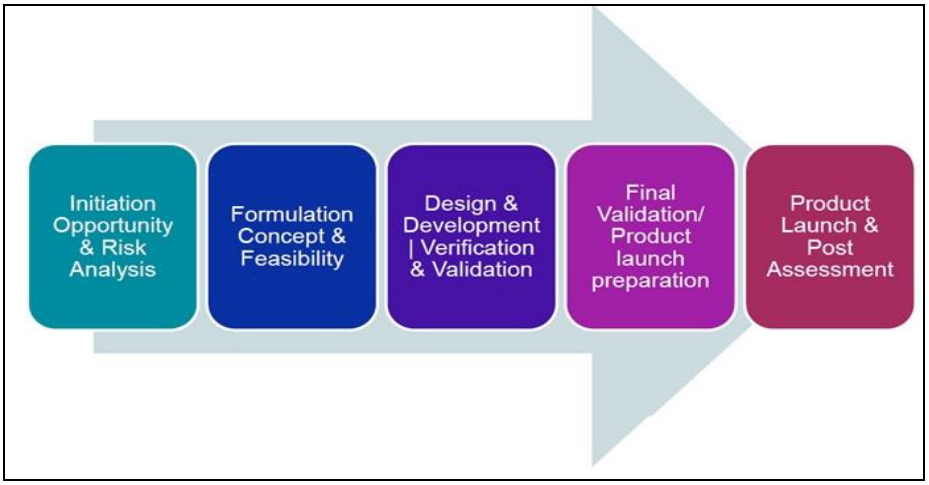

FIG. 4B: PHASES OF MEDICAL DEVICE DEVELOPMENT

It is here that clinical development strategies for medical device development have to be fully synchronized and integrated with and completely incorporated into the technology innovations. In other words, medical devices have to be conceptualized and developed, keeping in mind the intended value to be delivered to the end-user.

Technology, in itself, should not be forced into healthcare just for the sake of it unless there is a clear vision with respect to its integration with a medical device and its impact on healthcare. This is where the device development phases need a look.

a) Phase 1:

- ✓ The opportunity and risk analysis has to be defined
- ✓ Development journey has to be planned
- ✓ Budgeting and funding strategy has to be finalized
- ✓ Target markets – the where, how, and most importantly, why, need to be defined
- ✓ Thorough market research needs to be done on available equivalent or alternate therapy
- ✓ Quality management system and robust documentation needs to be implemented

b) Phase 2:

- ❖ Formulation, concept, and feasibility to be assessed
- ❖ Prototype development and proof of concept validation
- ❖ Voice of the customer has to be heard through surveys, competitor analysis, and market research
- ❖ Revise design over and over again till we are satisfied

c) Phase 3:

- ➢ Design and development verification, validation
- ➢ Device should withstand all the pressures of the real world
- ➢ Acceptance criteria need to be earmarked
- ➢ Design trace matrix needs to be set up
- ➢ Risk management strategy has to be in place
- ➢ Regulatory strategy needs to be clearly defined
- ➢ Clinical strategy needs to be defined with design freeze through actual use in a clinical setting

d) Phase 4:

- o Final validation and product launch preparation
- o Evidence generation for marketing claims
- o Comprehensive data collation
- o Scale-up – plan, and implementation
- o Technical documentation

e) Phase 5:

- ❖ Product launch and post-launch assessment
- ❖ Robust internal quality audit system
- ❖ Uncompromised production processes
- ❖ Implementation of QMS
- ❖ Changes only according to change control system
- ❖ Following feedback and complaints system
- ❖ Updating all necessary technical documentation as required
- ❖ Adequately resourced
- ❖ Continuous improvement

Often, a new device ‘working’ in a patient is the most exciting and rewarding aspect of the development cycle. A subsequent clinical trial can often be seen as exhausting, frustrating, expensive, and time-consuming. It is exactly at this juncture that we need to ask ourselves, is it necessary to conduct a trial of my new device. Rigorous risk

analysis needs to be done as to what exactly we are trying to accomplish. Post the proof-of-concept stage; no further learning is possible without human testing. We need to demonstrate product effectiveness to investors and raise additional funds. Enough data needs to be generated to improve the chances of selling intellectual property rights. Market awareness and exposure to the device need to be enhanced amongst limited key opinion leaders. Regulatory approval has to be obtained by conducting a pivotal study.

Importance of Post Marketing Surveillance (PMS): For a medical device to truly be successful and sustainable, PMS is necessary. The PMS plan may serve as a comprehensive tool for the benefit-risk evaluation of medical devices. If properly developed and implemented, it will function as a key player in establishing a new framework for proactive safety evaluation of medical devices. Recent public health safety issues involving medical devices have highlighted the need to update the European Union (EU) medical device regulation (MDR).

The Poly Implant Prothèse (PIP) breast implant scandal in 2012, for example, affected thousands of women and damaged the confidence of the different stakeholders involved PMS of medical devices. More than 400000 women around the world received PIP implants that were made of industrial-grade silicone gel, prone to rupture, leading to inflammation and irritation. The 2012 incident involving hip implants raised a public health concern - metal-on-metal total hip replacements were successfully implanted, but metal abrading against metal caused erosion and leaching of metal particles into soft tissue. Such metal debris weakens tissue and bone around the implant, leading to implant failure, requiring additional surgery. The manufacturers did not provide an adequate response to the competent authorities with regard to these adverse events, and there was always the belief that they could have been avoided [19]. As a consequence, various national competent authorities (NCAs) and other health organizations started focusing on strengthening post-market risk evaluation of medical devices. According to new regulations, any PMS plan needs to define the process for collecting, recording, and investigating complaints and reports from healthcare professionals, patients, and users on events suspected to be related to a medical device. A PMS system that is correctly designed should allow for early detection of possible malfunctions and/or complications of medical devices that may occur only after years or even decades of usage and implement appropriate risk minimization measures. To summarize, the new European Union (EU) PMS plan may serve as a thorough tool for the benefit-risk evaluation of medical devices. If properly developed and implemented, the EU PMS plan will function as a key player in establishing a new framework for the proactive safety evaluation of medical devices.

We Recommend the following to be included in the PMS Plan:

- A proactive and systematic process to collect data from characterizing device performance
- Effective and appropriate methods and processes to assess the collected data
- Effective and appropriate methods and tools to investigate complaints or market experiences collected in the field
- Methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators, and user
- Ensure optimal life cycle management
- Look out for expanded or new indications
- Implement inclusion in guidelines
- Support and build an economic value proposition
- Build local champions

Artificial Intelligence (AI) in Clinical Development:

The Future: Today, AI is set to transform healthcare product development with unlimited potential to benefit patients and other stakeholders, including regulators and industry. Rapid advances in this field pose new challenges. There are a number of opportunities for the use of AI in clinical

development and during the lifecycle management of healthcare products. Medical devices are no exception. For example, Using AI tools can be particularly helpful when a disease needs to be diagnosed from biological samples such as blood or tissue. These samples can be assessed locally without the need to transport them. Some of the foreseeable benefits of embracing AI into the fold of medical device product development are:

- Assessment of inclusion/exclusion criteria in clinical trials using AI tools
- Use of AI for identification of clinical activity in Phase II clinical trials
- Extraction of data from unstructured documents
- Automation of administrative work

However, increasingly complex devices and software, including AI technology, present regulatory authorities with progressively greater challenges to review. Some of the challenges are:

- Validation of AI-based software that is constantly 'learning'
- Assessment of safety signals from new AI based clinical endpoints
- Review of complex medical technologies which apply AI
- Who owns patient data

Nonetheless, AI offers opportunities to improve the development and application of medical devices in healthcare, with the potential to:

- Improve the robustness of data collected during clinical development
- Reduce the time and costs involved from discovery to market
- Reduce the workload for health authorities and industry
- Develop more innovative healthcare products [20, 21, 22, 23, 24].

CONCLUSION: In medical devices, a research prototype is never equivalent to a commercial product. For a device to be ultimately successful, it has to be safe enough, built by trained and skilled engineers, has to be usable by KOLs with guidance from the inventor, has to work during a demo, cost should not be a primary consideration, should be safe enough for the usage of our family member, built on the production line by workers at minimum wages, usable by clinicians, nurses, and technicians under high-stress environment, has to work every time and finally, must be cost-effective. Advances in the latest technology like AI needs to be synchronized right at the conceptualization stages for a medical device not just to see the light at the end of the day but also to leave behind a lasting legacy.

Source of Funding: There's no funding provided either from Abbott Vascular or Amity University to write this article.

ACKNOWLEDGEMENT: None

CONFLICTS OF INTEREST: Manish Narang and Dr. Krishna Sudhir are full-time employees of Abbott Vascular and have received the company stocks as well. Prof. Dr. Upendra Kaul is a full-time employee at Batra Hospital, Dr. Rama Manpreet Walia is a full-time employee of Amity University.

REFERENCES:

1. Brief History of Medical Devices and Regulations. https://www.winovia.com/brief-history-of-medical-devices-and-regulations/ accessed on 05 Aug 2021
2. Manz CR, Bekelman JE and Doshi JA: The Changing Characteristics of Technologies Covered by Medicare's New Technology Add-on Payment Program. JAMA Netw Open 2020; 3: 2012569.
3. Max Roser: Hannah Ritchie. Burden of Disease. Published online at Our World in Data. org. Retrieved from: 'https://ourworldindata.org/burden-of-disease' [Online Resource] Accessed on 05 Aug 2021.
4. A History of Medical Device Regulation & Oversight in the United States," U.S. Food & Drug Administration, 06/04/2019.https://www.fda.gov/medicaldevices/overview-device-regulation/history-medical-device-regulation oversight-united-statesAccessed on 05 Aug 21
5. Ex P and Henschke C: Changing payment instruments and the utilization of new medical technologies. Eur J Health Econ 2019; 20: 1029-1039.
6. Callahan A, Fries JA and Ré C: Medical device surveillance with electronic health records. npj Digit Med 2019.
7. Wilkinson B and van Boxtel R: The Medical Device Regulation of the European Union Intensifies Focus on Clinical Benefits of Devices. Ther Innov Regul Sci 2020; 54: 613-617.
8. Aronson JK, Heneghan C and Ferner RE: Medical Devices: Definition, Classification, and Regulatory Implications. Drug Saf 2020; 43: 83-93.

9. Hwang TJ, Sokolov E, Franklin JM and Kesselheim AS: Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study. BMJ 2016; 353: 3323.
10. Fleurence RL, Forrest CB and Shuren J: Strengthening the Evidence Base for Pediatric Medical Devices Using Real-World Data. J Pediatr 2019; 214: 209-211.
11. Altayyar SS: The Essential Principles of Safety and Effectiveness for Medical Devices and the Role of Standards. Med Devices (Auckl) 2020; 13: 49-55.
12. Tellez A, Ferrone M and Granada JF: Translational Research: The Cornerstone for Medical Technology Advancement. Toxicologic Pathology 2019; 47: 203-204.
13. Martelli N, Eskenazy D, Déan C, Pineau J, Prognon P, Chatellier G, Sapoval M, Pellerin O. New European Regulation for Medical Devices: What Is Changing. Cardio Vascular and Interventional Radiology 2019; 42: 1272-1278.
14. What is a Medical Device? Medical Devices and TWI.https://www.twi-global.com/technical-knowledge/faqs/faq-what-is-a-medical-device. Accessed on 05th Aug 2021
15. An overview of the medical device industry. http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0 Accessed on 05th Aug 2021.
16. Paulin J, Rousselle SD and Fossey S: Medical Device Histology and Pathology: A Horse of a Different Color. Toxicol Pathol 2019; 47: 201-02.
17. Xu H, Wang Y, Yang X and Li J: [Advances in Medical Device Standard System]. Zhongguo Yi Liao Qi Xie Za Zhi 2018; 42: 49-52.
18. Marešová P, Klímová B, Honegr J, Kuča K, Ibrahim WNH and Selamat A: Medical Device Development Process, and Associated Risks and Legislative Aspects-Systematic Review. Front Public Health 2020; 8: 308.
19. Hughes L, Chamberlain K, Robinson H, Sloan A, Choudry Q. Follow-up of Metal-on-Metal Hip Replacements at a Large Dis. Hospital and the Implementation of Medicines and Healthcare Products Regulatory Agency Guidelines A Review of 297 Patients. COS 2019; 11: 403-08.
20. Noncommunicable diseases. World Health Organisation. https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases Accessed on 05th Aug 2021.
21. Belkum, S, Brun, N, Cleve S, McGovern P, Lumpkin M, Schaeffer, Paul-Etienne, Pauli T, Trethowan, Jonathan and Netzer T: Artificial intelligence in clinical development and regulatory affairs – Preparing for the future. Regulatory Rapporteur 2018; 15: 17-21.
22. FDA permits marketing of clinical decision support software for alerting providers of a potential stroke in patients. U.S. Food & Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-clinical-decision-support-software-alerting-providers-potential-stroke Accessed on 05th Aug 2021.
23. Balthazar P, Harri P, Prater A and Safdar NM: Protecting Your Patients' Interests in the Era of Big Data, Artificial Intelligence and Predictive Analytics. J Am Coll Radiol 2018; 15: 580-86.
24. Heneghan CJ, Goldacre B and Onakpoya I: Trials of transvaginal mesh devices for pelvic organ prolapse: a systematic database review of the US FDA approval process. BMJ Open 7(12), e017125.

How to cite this article:
Narang M, Walia R, Kaul U and Sudhir K: Synchronizing clinical development strategy with technology innovations in medical devices. Int J Pharm Sci & Res 2021; 12(12): 6281-89. doi: 10.13040/IJPSR.0975-8232.12(12).6281-89.