THE LIFE CYCLE OF MEDICAL IMAGING TECHNOLOGY

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ABSTRACT

Knowing the life cycle of medical technologies plays a crucial role in the continued performance of medical technology used to treat and cure patients. To this end, we analyzed the characteristics of the non-invasive medical technology lifecycle, taking as a case study the medical imaging technologies (MIT). This paper examines this issue in a chronological manner, starting from the discovery of X rays (1895), the origin of the first medical imaging technology or computer tomography (CT) up to the modern hybrid medical imaging (PET CT, PET MRI). PET represents the positron emission tomography, and MRI is the magnetic resonance imaging. Thus, it has been identified the stage of MIT (CT, PET, MRI, PET-CT, PET, MRI) life cycle and found that traditional imaging (CT, MRI, PET) suffered multiple incremental improvements over time, currently being in a mature stage, while in the coming years it is expected to enter into a slow decline due to the increasing use of the hybrids (PET-CT, PET-MRI). The life cycle of medical imaging technologies is found in various stages: a) initial phase for PET-MRI, b) growth phase for PET-CT and c) the maturity phase for CT, MRI and PET, taken separately. MIT hybrid type revolutionized medical technology that has not changed in its essence for 40 years, relying only on incremental changes.

KEYWORDS: *life cycle of technology, medical imaging, non-invasive medical technology, MRI, PET, CT scan.*

1. INTRODUCTION

Medical technology has been defined by the World Health Organization (WHO) as "the application of knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and to improve quality of life" [1] .

Medical technology runs through four phases to marketing [2]: Phase 1 - initial preclinical studies or laboratory which do not involve human subjects; Phase 2 - studies on small groups of human volunteers; Phase 3 - studies on large groups of patients, more research centers, to determine the efficacy, benefits and risks arising from the new technology; Phase 4 - studies and post-marketing analysis, follows the evolution of technology during the entire life cycle. These phases are tightly controlled by government authorities in each country.

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There are two main features [2] important for medical technology development:

The first characteristic is that technological innovation in the medical field is a cumulative process. Progressive changes or modifications in the basic knowledge of certain technologies (incremental) at some point, not very different from existing versions, over a long period of time give rise to radical results in many areas. In the scanner case, based on X-rays, subsequent amendments were gradual, but within six to seven decades of research in various fields, including computers, have created a new brand of technology based on X-rays, known as CT scan (computer tomography).

The second characteristic considers that a new technology can come from a discovery or the development of a technology that originally had a particular purpose or had no medical purpose. For example, medical magnetic resonance imaging (MRI) has its origins in basic research in physics on nuclear magnetic resonance [2].

In addition, in TIM case computers hold an important role and computer technology is used to produce 3D images, to visualize anatomical structures and physiological delimitation. 3D images and the obtained data are sent to PACS (Picture Archiving and Communication Systems) network. PACS is a combination of hardware and software used for the storage, retrieval, management, distribution and presentation of images. Universal format for storing and transferring images is DICOM PACS (Digital Imaging and Communications in Medicine). The basic components of the PACS system outlined in Fig.1 are: a) a PACS server that consists of a computer (server) with large storage

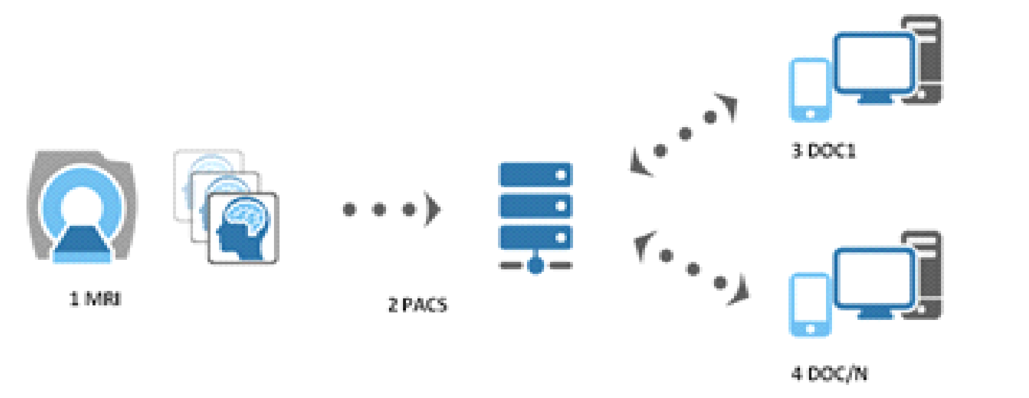

Figure 1. PACS system for processing and storage of images provided by the MIT [4].

space on hard disk for data input, b) software for transfer and archiving of DICOM images and c) a PACS Client consisting of a computer with specialized software (DICOM viewer) to view the image in DICOM format. [3]

2. THE LIFE CYCLE OF TECHNOLOGY (LCT)

The life cycle of a technology describes how the technology influences the life stages of products and the impact of technology in the business of research and development stage, including the stages of growth, maturity and the decline to technology. Life cycle describes also the commercial gains of a technology incorporated into a product or process. The life cycle of technology actually describes the time travel of the technology. The technology is born and grows up to its inevitable decline and eventually to death.

Understanding the life cycle of a technology helps to predict the ability of recovering the investment made for the development of such technologies, and when to plan new projects. Thus, the life cycle of a technology is a useful tool for estimating future development of a specific technology and to take the decision whether or not to invest in it.

2.1. S-curve of the life cycle of technology visually illustrates how the technology evolves over time.

S-curves are usually connected to "market adoption". The S curve concept is applied to the life cycle of technology and seeks to limit the performance that can be achieved by technology, as the performance may increase continuously and indefinitely. [5-14]. In

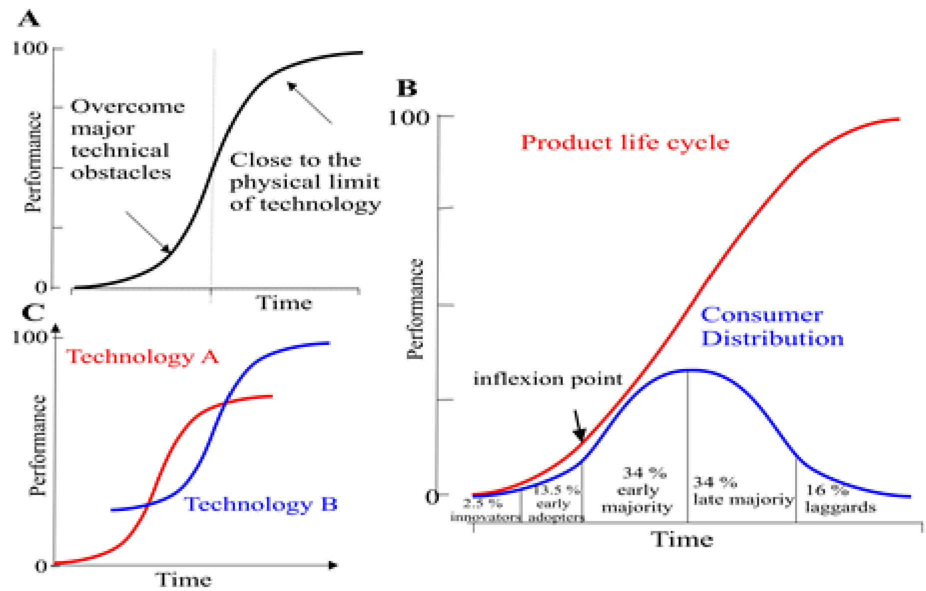

Figure 2. A. S-curve improves the performance of a technology. B. Technology adoption curve vs. S-curve. C. Double S curves describe the transition from one technology to another.

Fig. 2a is plotted the technology performance against the amount of effort and/or the money invested in technology. It shows initially a slow improvement in performance, followed by an increase, then a decrease in performance. Improving performance in the early stages of technology is slow because the fundamentals of technology are still not well understood. But with a better understanding of technology, it begins to accelerate improvement, increasing the performance per unit of effort. At one point, the technology will reach its inherent limits. **Fig. 2b** shows the S-curve of lifecycle technology that signals a possible discontinuity in an emerging technology that replaces a mature technology. The beginning curve highlights the birth of new market opportunities, while the end of the curve shows the death or obsolescence of the technology market. Usually at the end of an old S-curve emerges a new S curve. For example, the endoscopy invasive diagnostic is replaced by the non-invasive diagnosis based on medical imaging. In this situation there is a "breakthrough" technology in medical technology. Technological progress will generate a succession of S-curves. In Figure 2c an S-curve is used to describe the spread of technology. Unlike the S curve used to show performance technology [14], the S curve used to show the diffusion of technology is obtained by plotting a cumulative number of adopters of technology over time. Adoption is slow initially, when a new technology is introduced on the market and accelerates as the technology is better understood and used in mass until the market is saturated, so the rate of adoption will be in decline.

Managers can use the model of S-curve as a tool to predict when a technology reaches its limits and it is used as a guide in the timing of when a company should move to a new technology or identify radical new technologies. S curve model limitations as a tool bar are:

1. First, it is rare when the true limits of a technology are known in advance, and there is a considerable disagreement among companies about the limitations of the technology;

2. Secondly, the S-curve of a technology is not set in stone. Unexpected changes occurred in the market for components and complementary technologies can shorten or extend the lifecycle of existing technologies;

3. Furthermore, the firms can influence the shape of the S curve through their activities of scientific research and development.

2.2. Mathematical modeling of lifecycle technology. The precise form of LCT depends on the type of product's sales curve, market, product policy, specifically the marketing mix and competition [5]. The various analyzes carried out on concrete data sets revealed that such curves correspond to an exponential function Y (t) as:

$$\mathbf{Y(t) = kt^{a}\, e^{-bt}}$$

where Y(t) represents the sales at time t, a and b are specific parameters of the product and market **(Fig.3).**

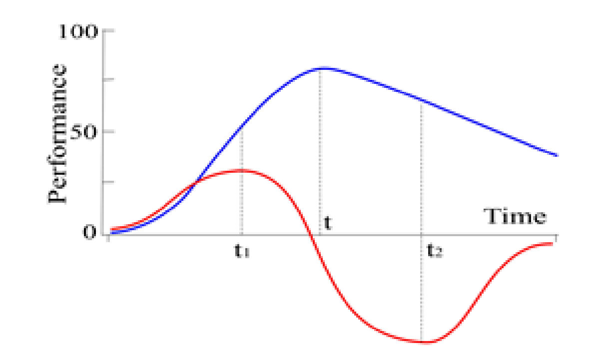

Figure 3. Features of the life cycle of technology [5]

3. THE STUDY OF THE LIFECYCLE OF MEDICAL IMAGING TECHNOLOGIES

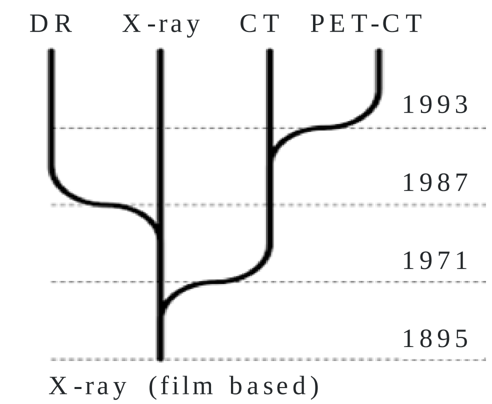

Figure 4. X-ray Imaging [15].

Innovation in the field of X-rays has led to changes in the organization of healthcare in all countries, the specialty of radiology was established officially in 1930. X-ray Technology (Fig. 4) diffused rapidly and continued to generate the largest MIT income. Since the discovery of X rays, the new MIT are relying on the experience of the previous generation of potential adopters. New users of CT scanners had expectations based on their experience with X-ray scanners and the new users of MRI have expectations based on their experience in using the CT scan type.

3.1. Medical imaging with computed tomography (CT)

CT scanner is a diagnostic tool that combines X-ray equipment with a computer and a cathode ray tube to produce images of cross sections of the human body. In the early stages of this technology a large sum of money was spent on research and development and required many years to produce the first commercial prototype, which was marketed by company EMI Co. in 1972. Since then the technology underwent many incremental improvements (Figure 5) and is currently leading the seventh generation of CT scanners [15,16]. Once the technology has reached a certain level of development, know-how and expertise began to spread. The S curve of this technology diffused rapidly because of the existence of a vacuum to market area; at present this technology is in a mature stage. Statistical data on this technology market in recent years shows that it is in balance with very small oscillations, the S-curve in the coming years is expected to show a decline of this technology.

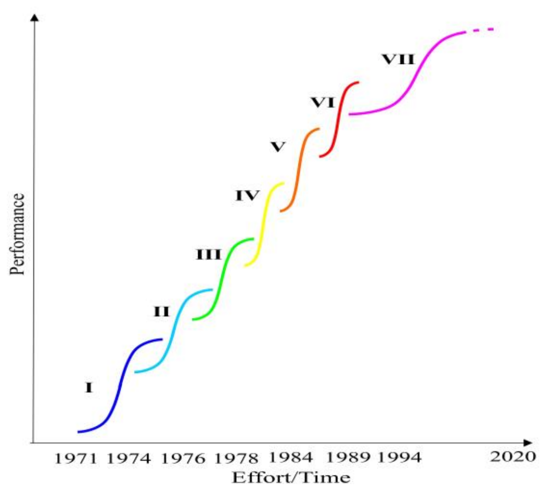

Figure 5. Multiple S curves on the evolution of computerized tomography (CT).

3.2. Medical magnetic resonance imaging (MRI). MRI is the innovation in the field of medical imaging based on magnetic resonance imaging. The first image produced by an MRI scanner type Lauterbur was obtained in 1973. Prototypes of MRI scanners have been developed in the United States, England and the Netherlands, at the end of 1977 [17,18]. In 1980 it began marketing the MRI scanner. Despite its technological potential, the initial distribution of the MRI scanners were slower than of the CT scanners. The causes of this situation is the existence of partial similarity of images obtained by the two types of technology, and the higher cost of MRI scanners compared to the CT scanners and the fact that new technology principles were not well understood [19]. The introduction and dissemination of this technology were slowed because of the economic recession of the early 80s and after this period it was recorded a growth in MRI market [20]. Between 1993-1997 there was a slight slowdown in the adoption of MRI [21,22], because of the introduction of health care management activities in the US. But with a deeper understanding of the technology, its dissemination begins to accelerate. After 1997 this technology has been on the upward curve. MRI over time suffered a series of incremental improvements (Figure 6), achieving scanners increasingly more efficient, from 0.5 T (Tesla) to 3 T, while in the evaluation phase are the 7 T and in the research phase the 11,5-20 T [23]. In the coming years it is expected a slow decline of this technology.

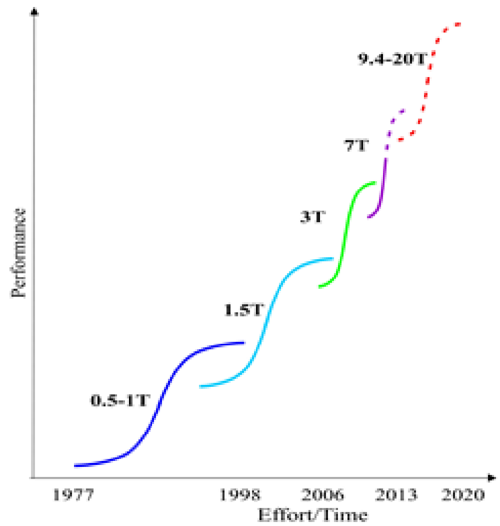

Figure 6. Multiple S curves on the evolution of magnetic resonance imaging (MRI).

3.3. Medical imaging by positron emission tomography (PET)

PET is a functional method by which images are created through isotopically labeled molecules with positron emission, which restores the body's biochemical processes. In 1953, the first PET image was obtained. The first PET scanner type was built for human studies by Edward Hoffman in 1973 [24,25]. 1975 was the first commercialized PET scanner, since until now these PET scanners have undergone incremental innovations to improve performance.

Imaging technologies (CT, MRI and PET) provide information about the operating status of the body via a visual display. The three technologies had undergone incremental innovations, currently being in the mature stage of the LCT.

3.4. Hybrid medical imaging

In the late 90s there was a new approach to medical imaging, the hybrid medical imaging [32]. This type of imaging is defined as a fusion of two or more MITs in one new form of synergistic imaging (PET-CT, PET-MRI).

3.4.1. Hybrid imaging PET-CT

In 1999, it appeared the first prototype of hybrid imaging PET-CT, built by combining

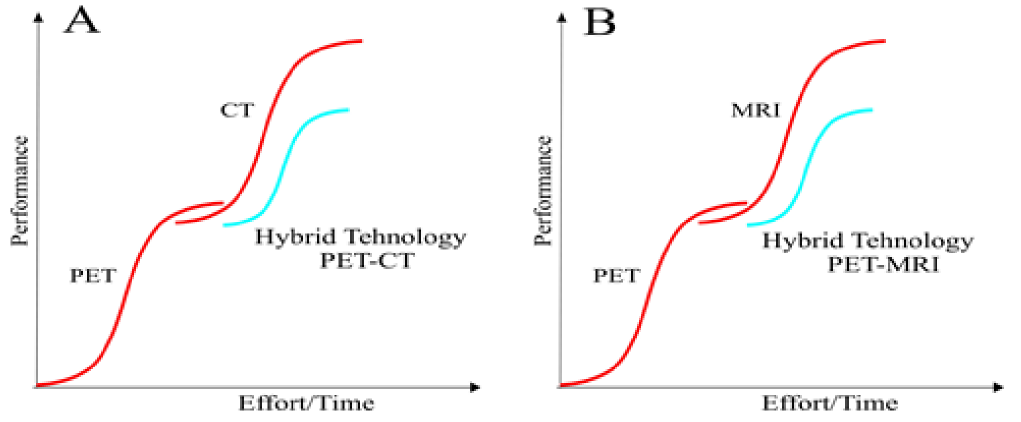

Figure 7. MIT S-curves for hybrid technologies PET-CT & PET-MRI.

PET scanners PET with CT, that obtained images of functional (PET) along with morphological information (CT) within the same image (Fig. 7). The first hybrid scanner PET-CT was sold in 2001. Over the decade, this technology was improved by incremental innovations, this hibid is currently in the growth phase of the life cycle of technology [26].

3.4.2. Hybrid imaging PET-MRI

PET-MRI is a high technology product obtained by incorporating PET scanners in MRI devices with magnetic field (Tesla) (figure 7b), resulting in the most accurate medical diagnostic imaging device. Development of hybrid PET-MRI in a single system started in the late 90s. After a period of 15 years PET-MRI is available for sale. In 2008 it was created the first hybrid PET-MRI prototype by Siemens. In 2012, the company MR Solutions Ltd. developed the first PET-MRI scanner, the world's top high-performance magnetic field 3T. A stronger range than 7 Tesla followed in 2014 [27].

Initiation of PET-MRI integration was based on the huge success of the combination of PET-CT. One of the reasons for the slow progress of this hybrid is the complexity of the technical integration of PET and MRI due to the presence of magnetic fields [28,29] and another is the high cost of a PET-MRI scanner. Currently, hospitals are facing substantial costs for procurement of integrated PET-MRI technologies, including the construction or renovation necessary to match the physical demands of the combined system and installing medical equipment required during imaging procedures. This new hybrid technology has been accepted by innovators and early adopters, being now in "chasm" phase (Figure 8), and to overcome this obstacle is necessary to develop a market strategy so that to pass the early adopters and the technology to survive in order to enter the market. This technology is in competition with the hybrid technology of PET-CT, these two technologies are found in a situation similar to that in the 80 -90, when MRI and CT scan competed.

3.5. The role of lifecycle adopting technology (LCAT), Hype cycle's S-curve in the conceptualization and possible scenarios of sustainable technology.

M. Rogers (2003) and G. Moore (2014) showed how to make the transition from a market dominated by a few customers (early visionaries) to a mass market dominated by a large group of customers who are pragmatic in orientation [30,31]. M. Rogers classified the technology life cycle stages as relative percentages of customers which adopt the technology in each stage. Initially are the innovators (2.5%) and early followers (13.5%) who are primarily concerned with the underlying technology and its performance. Then, comes successively the early majority (34%) and the late majority (34%) and finally the skeptics (16%); all of whom are more interested in solutions and comfort. Lifecycle on the adoption of technology takes the form of a bell curve used to understand how the acceptance of new technologies takes place. G. Moore relying on work by M. Rogers introduced the concept of chasm (fig. 8; gulf), that is located between the early followers and early majority, and it describes the point where a new technology "dies" or "survives", when it may or may not disappoint the adopters of new technology, depending on the performance of this technology to obtain revenue through its sales.

In 1995, Gartner coined the term "hype cycle" for the route of the new technologies-from the occurrence until maturity. Cycle expectations (hype) show the events happening around the introduction of new technologies or the discovery/innovation, tip inflated expectations, disillusionment (low confidence), lighting (slope productivity) and the plateau of productivity [32,33]. New technologies undergo through a cycle of adoption, when early adopters will adopt a new technology, but it can be blocked by a vacuum. This gap is referred to as the "death valley" and overlaps with the "chasm" (gap) that is found on the lifecycle adopting technology. Companies need financial resources to develop these new technologies until the performance will generate sufficient revenues. It is recommended for continuous investing of financial resources, that crossing the chasm ("death valley") should be done by segmenting the market, creating a niche in a larger market, where medical technology is recommended by the excellence in accuracy on diagnosis of a certain type of disease (eg. oncology, cardiology or neurology) and attacking competitors on small segments through proper positioning.

It is important for references that the number of customers who buy/use the technology to be growing. Once past this gulf ("death valley"), companies can afford to focus on other market segments. Sustainability depends on overcoming this technology to reach early majority. When most early starters use the technology, the hype cycle follows a slope of enlightenment (productivity), which will positively influence the decision of others to adopt this technology. Most late adopters (skeptics) then begin to adopt the technology.

3.5.1. Place occupied by medical imaging technologies (MITs) along cycle expectations (hype), lifecycle for adoption of technology (LCAT) and curve S.

3.5.1.1. Traditional medical imaging technologies CT, MRI and PET are shown when the maturity curve S, being adopted with delay (by skeptics) on the life cycle curve of technology adoption and along the cycle expectations (hype) is on the productivity plateau. It is expected to enter the decline phase, but this will happen slowly (Figure 8).

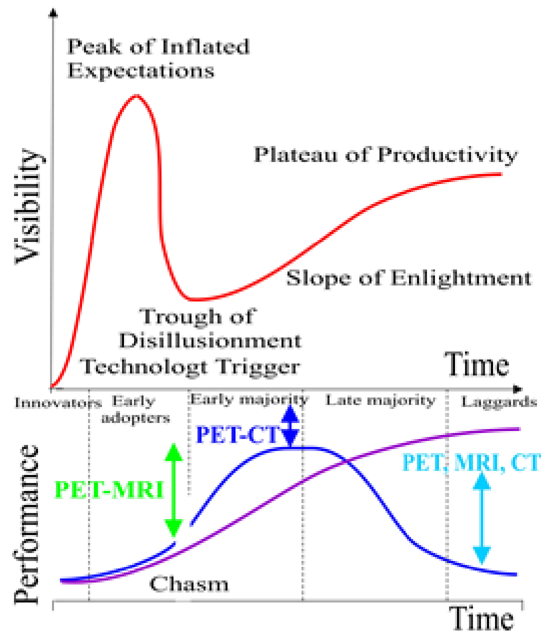

Figure 8. Hype cycle curve vs. S-curve LCAT and medical imaging technology.

3.5.1.2. Hybrid medical imaging technologies PET-CT & PET-MRI

PET-CT is in the growth phase of the S-curve, adopted by the early majority and it is at the time of adoption by most late adopters in the life cycle curve on the adoption of technology, while along the cycle expectations (hype) is located on the slope of productivity (Figure 8). Progressive development of this type of technology has the opposite effect on traditional TIM, increasing the pace of their decline.

PET-MRI is in the beginning phase of growth on the S-curve of the life cycle curve for adoption of technology, when it is accepted by early adopters and is facing the abyss. It should pass this stage to be adopted by the early majority and the expectations over the cycle (hype) that is in front of the "death valley"/low confidence (Figure 8). It must exceed this valley in order to be on the slope of productivity, the future evolution of this type of technology depends on medical performance increase, medical cost reduction and the financial resources invested by government authorities, public companies/private and public.

In recent years, policymakers are trying to gather information about emerging medical technologies and healthcare before they reach the market. Pre-release information on the cost-benefit, risk, effectiveness are modeled (influenced) by mechanisms regulating medical devices and health technologies. There are government agencies, consortia of stakeholders who are actively involved in healthcare technology assessment (HTA). Companies that come with new technologies must know this trend and be prepared to overcome this obstacle. A strategy needs to be designed so as to survive the early adopters and technology would enter the market. In this situation is the hybrid PET-MRI technology [34-37].

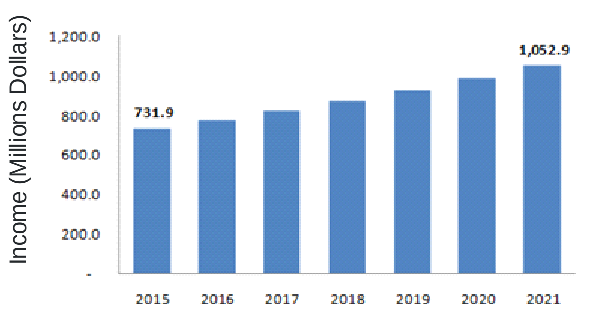

Figure 9. The global market for medical imaging during 2015-2021. [From Ref. 39]

Global medical imaging market is expected to grow from 731.9 million dollars in 2015 to 1.0529 billion dollars respectively in 2021 at a CAGR of 6.30% between 2016 and 2021 (Fig. 9). The clinical use of medical imaging has grown rapidly in all phases of the clinical trial. This report studies the market potential of services and software for diagnostic imaging, and research and development [38,39].

4. CONCLUSION

Recently, medical imaging technology has become a tool increasingly specific, in both sensitivity and specificity, largely due to the creation of 3D images. 3D imaging helps significantly to understand diseases through: management, diagnosis, treatment and prevention, so that we can better assess pathology of disease and to intervene much earlier in their treatment. Accelerating the pace of innovation in medicine is inspiring hope for a better medical care. Now we can monitor the improvements in medical imaging allowing us to see even the biochemical changes that occur at the onset of disease. Medical imaging allows a broader understanding of human vision disease, by providing an accurate diagnosis. In the future, MIT innovations will play an important role in the development of medical science. In this article we studied the MIT of CT, MRI and PET, as well as the PET-CT hybrid and PET-MRI types. The life cycle of medical imaging technologies is found in various stages, like: a) the introduction of PET-MRI, b) the growing of PET-CT, and c) the maturity of CT, MRI and PET. The adoption of these technologies is carried out along a period of time, requiring preclinical and clinical studies on the efficacy and safety. Medical imaging technologies have diffused to new generations based on their previous experience. Users of CT scanners anticipated the "death valley" gap that new technologies are facing, based on their experience with X-rays; MRI users have relied on their experience in using CT scanners, while PET-MRI users were based on their experience in handling PET-CT scanners. In turn, all these technologies underwent numerous incremental innovations. An interesting case is the competition between CT and MRI, PET-CT and respectively PET-MRI. These differences can be summarized in four basic categories: i) scanning technology, ii) targeted anatomical region suitability, iii) safety, and iv) cost considerations. MITs are advanced and reliable technologies that have distinct advantages, but also have some disadvantages to be taken into account in the design and the development of elements for study protocol acquisition. Understanding how each technology works is a priority in designing a successful clinical trial.

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