

STUDY ON INDUSTRY OUTLOOK OF DIGITAL PATHOLOGY

Dissertation Submitted to



The IIHMR University, Jaipur
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in
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Management/Rural Management
by

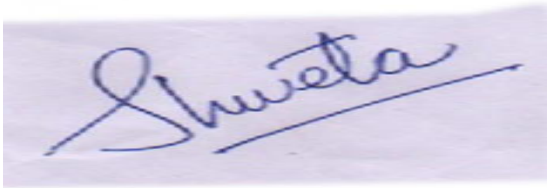
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Under the Supervision and Guidance of

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2021

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Study on Industry outlook of Digital Pathology** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

A handwritten signature in blue ink on a light purple background. The signature is cursive and reads "Shweta".

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Name of

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CERTIFICATE

This is to certify that **Shweta Bisht** in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural Management) from the IIHMR University, Jaipur has successfully completed her/his internship at **Grand View Research India PVT LTD**, Pune during April 5th, 2021 to June 19, 2021.

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This is to certify that dissertation title Study on Industry outlook of Digital Pathology is a record of the research work undertaken by **Shweta Bisht** in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

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I wish to expand on my expertise and skills to contribute to the industry in the future.

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ABBREVIATIONS

Acronyms	Definition
DP	Digital Pathology
DPS	Digital Pathology System
WSS	Whole Slide Scanner
WSI	Whole Slide Imaging
GVC	Global Value Chain
MUMPS	Massachusetts General Hospital Utility Programming System
FDA	Food & Drug Administration
CLIA	Clinical Laboratory Improvement Amendments
LIS	Laboratory Information System
PACS	Picture Archiving and Communication System
CMS	Centers for Medicare and Medicaid Services
CFR	Code of Federal Regulations
CAP	College of American Pathologists
DEM	Digital Electron Microscopy
VSV	Virtual Slide Viewer

1. ABSTRACT

The global digital pathology market is booming as the healthcare business spends more money. Various countries, including the United States, Canada, and Germany, are promoting technologically advanced healthcare items in order to give better healthcare to their people. Digital pathology is used in a variety of settings, including diagnostic facilities, academic research, and drug discovery and development. There has been an increase in the number of cancer cases, which has resulted in longer diagnosis and treatment wait times. One of the factors driving market expansion is rapid technical advancements in digital pathology systems. However, due to the pandemic, the majority of pathological tests performed around the world has decreased. Furthermore, demand for these solutions has been hurt by the global lockdowns and bans established in 2020. In the current and prospective climates, digital pathology can help to preserve healthcare services and pathology-based research.

2. INTRODUCTION

Digital pathology, also known as virtual microscopy, is the process of capturing, maintaining, analyzing, and decoding virtual data from a glass slide. While glass slides are acquired with a scanning instrument, digital slides are made to provide a high-resolution virtual image that may be viewed on a computer display or a mobile device. Using specialized digital pathology software tools, digitized slides can be transferred over networks. To aid in the interpretation and measurement of biomarker expression within tissue slices, automated image analysis technologies can be used.

Pathologists are in short supply, with more pathologists retiring than joining the profession. The adoption of digital technology has increased, resulting in higher quality and innovation.

Digital pathology has the potential to significantly improve quality. One of the most significant advantages of digital pathology is the several ways in which it boosts productivity both in the short and long term.

2.1 Executive Summary

The research project "Study on Industry Outlook of Digital Pathology Market" defines and segments the market in different regions. With the analysis of trends, opportunities, and constraints, it also provides drivers and restraints for the digital pathology industry. This research study uses a secondary technique to extract and collect data, with data drawn from a variety of research papers, reports, journals, websites, books, and other sources.

The digital pathology market has been segmented based on technology, applications, and geography. In the first segment, the market is divided into two categories based on technology: whole slide imaging and telepathology. In the second segment, the market is divided into three categories based on application: drug discovery and development, academic research, and diagnosis. The third segment comprise North America, Europe, Asia-Pacific, Latin America, the Middle East, and Africa.

The aim of this project is to investigate the concept of digital pathology and its market in various locations, as well as to determine the overall demand for digital pathology across various industries. The study of the digital pathology market reveals the importance of putting more emphasis on enhancing workflow efficiency and developing faster diagnostic tools for chronic diseases. It's an innovation that aims to reduce laboratory expenses, improve operational efficiency, boost productivity, and enhance treatment decisions and patient care. In 2020, the global digital pathology market was estimated to be worth USD 386.2 million.

The study also investigated the market using PESTEL and PORTER'S Analysis to identify the level of competition in the industry and the formulation of company strategies. It covers market demand, digital pathology system applications, regional segmentation, and competitor and strategy overviews.

About the Project

The research for the project is based on market research. The systematic, objective collecting and analysis of data on competition, and/or environment, the specific target market is known as market research. Whether primary research or secondary research, it always includes some form of data collecting that is acquired directly from a responder.

This market research study aims to improve understanding of the global digital pathology market. As marketplaces around the world become increasingly competitive, market research has never been more vital for all businesses, large and small. This research assesses the overall market's viability and identifies the most important tool for changing business strategies (such as communication, pricing policy, products, range, and competition) in order to achieve the best outcomes and meet the desired objective.

Digital pathology's concept and functionality are rapidly evolving, and now include digital specimen visualization, real-time evaluation, electronic management of two- and three-dimensional specimens, comparison, two- to three-dimensional reconstruction, archiving, and dissemination for consultation and widespread viewing. Data can be combined with that of other patients, mined, and used for educational purposes, clinical diagnosis, and patient management, as well as research. Implementation challenges exist, but they are surmountable and well worth the effort.

The below are some characteristics of market research report:

- Geography: local, regional, national, or international market
- Chronological/time-oriented: past, and present
- The competitors' profile:

2.2 Overview of the Digital Pathology Market

Digital pathology (DP) is defined as a dynamic, image-based system that allows pathology information to be acquired, managed, and interpreted from a digitized glass slide. Digital pathology is the process of scanning standard slides and tissue samples that would have been examined under a microscope into a digital image that can be viewed on a computer screen for the most accurate comprehension and analysis. A whole slide scanner (WSS), image viewing and database software, image acquisition software, image analysis software, and the requisite IT infrastructure are all included in the Digital Pathology System (DPS).

The field of digital pathology has exploded since the introduction of Whole-Slide Imaging, but is now regarded as one of the most promising avenues of diagnostic medicine for achieving even faster, better and less expensive prognosis, diagnosis and prediction of cancer and other serious diseases.

Traditional microscopy can be augmented by digital pathology only one slide may be viewed at a time under a microscope in classical microscopy. One can view many digital slides on a computer monitor in digital pathology. In digital pathology, disseminating information is also simple. Anyone can instantly share the information with anyone in the world. Integrating a digital pathology system with a laboratory information system is also reasonably simple.

In digital pathology systems, technological advancement is increasing rapidly and is one of the factors driving the market's growth. Robotic light microscopy, digital photography, computerization along with several fiber optic linkages are all contributing to propel the industry forward. Whole slide imaging is one such technology that has several advantages over typical light microscopes and is expected to generate lucrative opportunities in this sector.

Market is divided, by product, into the Whole Slide Imaging and Telepathology. In 2019, the whole slide imaging dominates the market. Whole slide imaging (WSI), often known as "virtual" or "wide-field microscopy," is the process of digitizing glass slides in order to replicate light microscopy. WSI produces significant digital images by scanning glass slides of various samples at several magnifications and focal planes at a relatively fast speed (x, y and z axes). The primary contributors to market growth include increased usage of this technology for academic research activities and improved resolution. This approach is expected to grow significantly due to advances in magnification and scanning of slides at the Z axis, which are given by whole slide imaging.

Telepathology is still in its early stages of adoption, accounting for a modest proportion of the market in 2020. The expensive cost of software implementation and maintenance, as well as the complexity of the system, security concerns, inconvenient slide selection, and set-up costs, are all stumbling blocks to its adoption in the medical area. Improvements in service delivery, patient safety, and communication, as well as decrease mistake rates, cheaper costs, and better and more effective data utilization, are all possible benefits of digital pathology.

The market is divided into two categories based on application: academic research, drug discovery and development and diagnosis. North America, Latin America, Europe Asia-Pacific, Africa and the Middle East are the primary geographic regions in which the global digital pathology market can be categorized.

2.3 Objective of the Research: -

The objective of study was to understand the current status of digital pathology globally.

- To study the market segmentation of the digital pathology market by technology, application, and geography (all continents).
- To understand the various factor affecting the growth of market i.e., drivers and restraints
- Identify the challenges and opportunities for market growth
- To study the Covid-19 Impact on digital pathology market

2.4 Scope of the Project

Pathology, like most medical specialties, is witnessing an increasing need to patient safety, improve quality and diagnostic accuracy as a result of the increased emphasis on sub-specialization. These factors, combined with the need to consolidate and centralize diagnostic services due to financial restrictions, are driving the development of systems that could increase access to expert opinion and highly specialized pathology services.

An anatomic pathologist's various tasks include diagnosis, consulting, documentation, and education.

Pathology is a visual discipline, it is necessary to integrate high-resolution digital images in lectures, teaching materials, and electronic papers. Reports become more accurate and concise when they are combined with synoptic writings. Block keys and hand-drawn schematics can also be replaced with digital pictures. Digital photography has changed the presentation of pathology reports in this way, allowing for the inclusion of colorful photos of the gross material as well as essential microscopic data.

Digital pathology is a dynamic, image-based system for acquiring, managing, and interpreting pathology data derived from digitized glass slides. In pathology, digital imaging is more of an evolution than a revolution these days. As clinical trials (e.g., teleconferencing) become more popular, pathologists are beginning to engage more with one another. However, additional interaction between digital photo frames and computer systems, as well as standards for the entire digital photography process, are needed.

Digital pathology is proving to have significant benefits for healthcare practitioners, but rising usage is also not posing any new obstacles to these early adopters. Challenges include insufficient funds for the technical setup, technical faults, and a lack of competent staff, to name a few.

3. Digital Pathology Market- Global Analysis

Digital pathology is used in a range of locations, including diagnostic facilities, academic research, and drug discovery and development. Due to its vast applications in various research methods such as biomarker profiling and tumor morphological study, the academic research sector dominated the market.

The global digital pathology market is booming as the healthcare industry spends more money. Various countries, such as the United States, Canada, and Germany, are boosting their support for technologically advanced healthcare items in order to better serve their citizens. As a result, digital pathology is becoming more widely used in both developed and developing nations.

Table 2. Global Digital Pathology Market Regional Analysis 2020

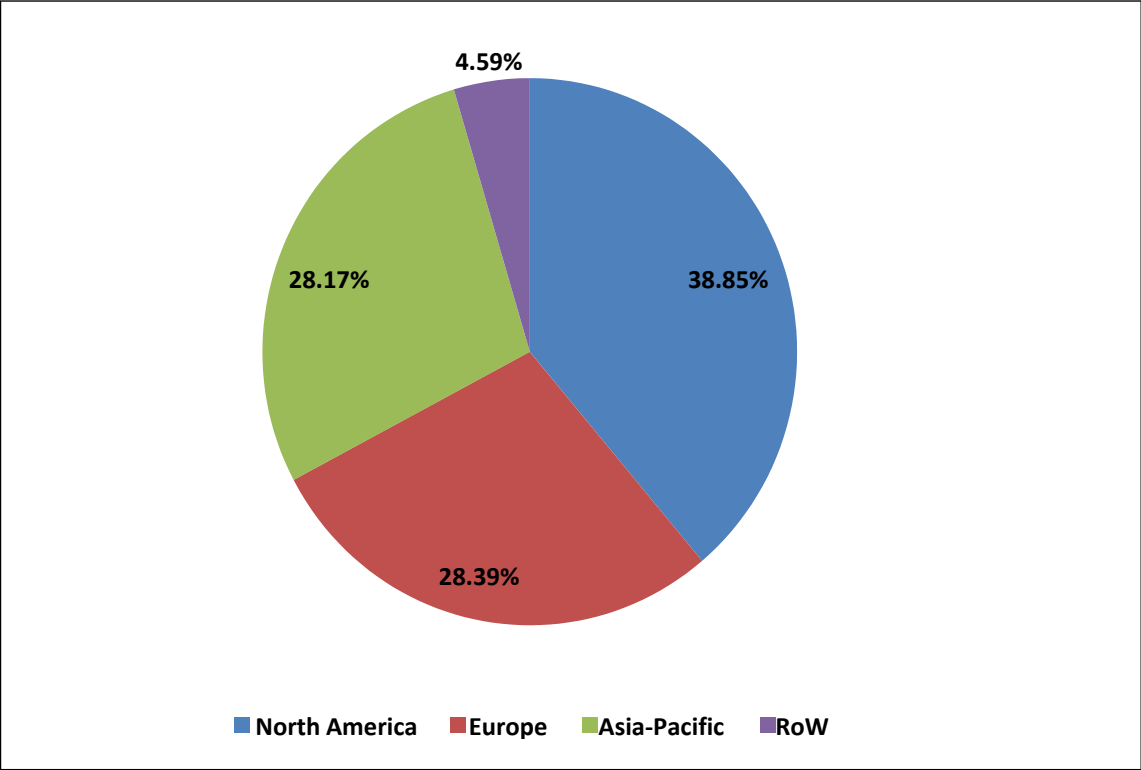
Region	Market share 2020 (USD Million)	Market share 2020(percentage)
North America	150	38.85%
Europe	109.5815	28.39%
Asia	108.719	28.17%
RoW	17.73	4.59%

(Source
: data
collecte
d by
researc
her
after
studying
various
reports)

In North America, the largest manufacturers within the digital pathology market are Leica Biosystems (parent company Danaher), General Electric, Definers, Olympus corporation, Ventana (Roche), Hamamatsu and Philips global. The continuous deployment of R&D investments, efforts linked to the development of technologically advanced systems, supportive government increased acceptance of digital imaging, and the existence of large players in this location are the main contributors to its dominance.

The Asia-Pacific region is expected to witness the fastest growth in the coming years due to expand of penetration of digital imaging in developing countries, investments in the medical field are increasing and the presence of undiscovered potential. Due to the extreme growing prevalence of cancer, which affects a huge population, the Asia Pacific healthcare industry has had a significant impact on the digital pathology market.

Figure 4. Global Digital Pathology Market Analysis 2020



Interpretation: -

The global digital pathology market currently dominates global security, with North America and Europe accounting for the majority of market share. North America accounted for 38.85% of the entire worldwide digital pathology market, while Europe had a 28.39 % share. Asia-Pacific had a 28.17% market share.

Increased use of digital pathology for disease detection and advantageous reimbursement regulations in the United States are likely to boost industry growth in this region, improving the quality of cancer diagnosis.

4. Literature Review

Digital Pathology was held back by insufficient programming tools and computer technology. The World Wide Web's emergence in the 1990s paved the way for the widespread design and use of data transmission networks, which is now considered one of the cornerstones of digital pathology.

The history of telepathology covers about 40 years, with highlights including:

- Robotic telepathology was demonstrated utilizing color video via satellite between Texas and Washington, D.C. in 1986.
- Norway established a nationwide telepathology programmes for frozen section services in 1989.
- Hardware for a comprehensive telepathology system became available in 1994. WSI comes to market in the year 2000.

- In 2009, an FDA panel met to discuss whether digital pathology should be approved for primary diagnosis.

Telepathology is now used for tele hematology and ultra-structural (digital electron microscopy) telepathology, in addition to surgical pathology.

5.1 Evolution of Digital Pathology: -

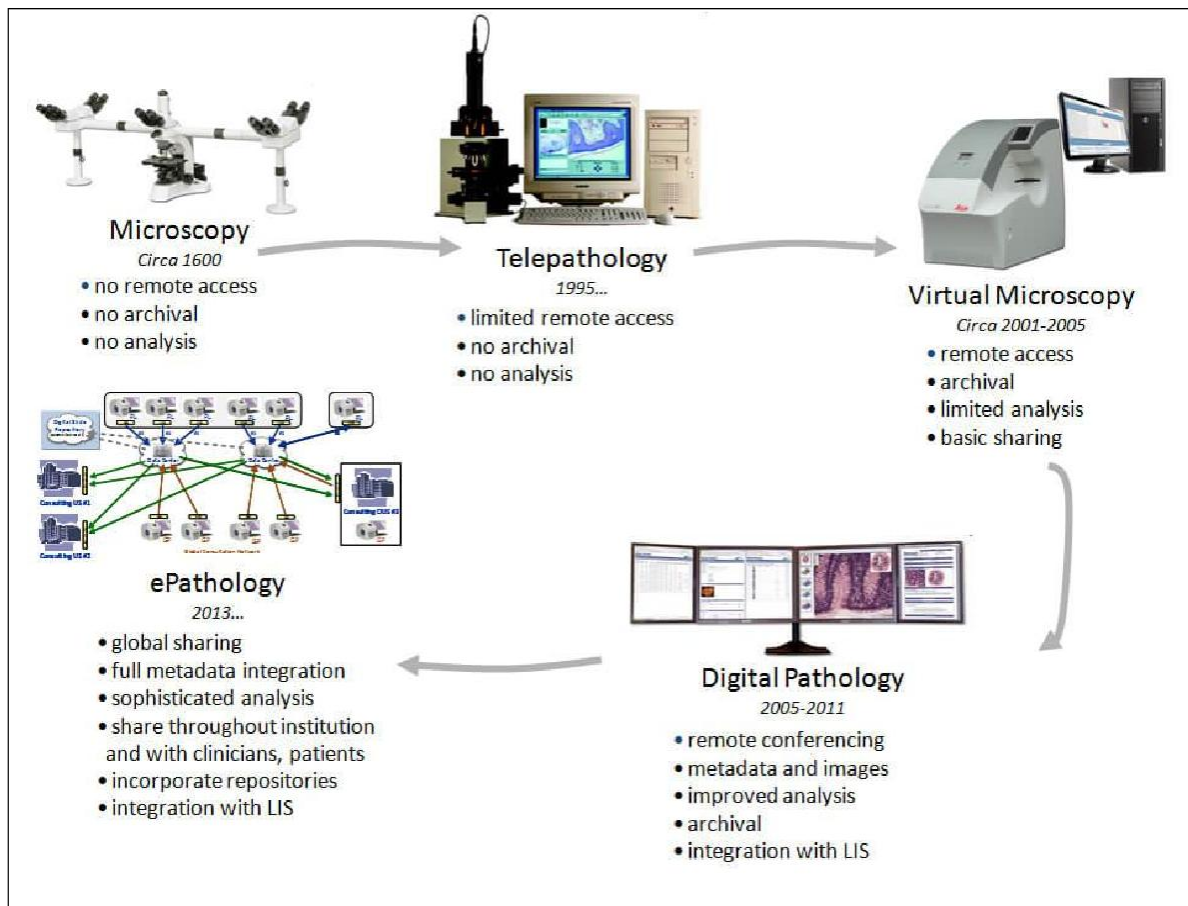


Figure 3. Evolution of Digital Pathology

5.2 Research Design

The research design can be thought of as the blueprint for the research endeavor, outlining each step in the process. Market research is a method of gaining a broad understanding of what consumers want, need, and believe. It may also entail observing their behavior. Market research, according to Drucker (1974), is the quintessence of marketing since it can be utilized to determine how a product should be marketed.

In this project we are **using Secondary Research that is secondary data collection method.**

5.3 Data Collection

Secondary research was done through internet articles and online blogs, company annual reports and industry practices, websites.

5.4 Data Analysis Tool

Data is Analyzed using statistical tool Microsoft Excel for organizing numerical data, calculation of percentage and preparing pie-charts.

6 Data Analysis and Interpretation

This chapter helps to explain the analysis of digital pathology market. It includes the following factors:

1. Industry Outlook
 - Market Segmentation
 - Digital Pathology - Value Chain Analysis
 - Digital Pathology – Drivers and Restraints
 - Market Dynamics
 - Increasing Application of digital pathology in Various Industries
 - Porter's Analysis
 - Digital Pathology Market – PESTEL Analysis
2. Competitive Analysis

Industry Outlook

6.1 Market Segmentation

Figure 5. Digital Pathology Market Segmentation

Interpretation: -

The digital pathology market is divided into three categories: technology, application, and geography. The market is divided into two segments based on technology, the first of which includes whole slide imaging and telepathology.

6.1.1 Market Segmentation by Technology

- **Whole slide imaging (WSI)**, often known as "virtual microscopy," is the process of scanning, storing, transferring, and posting diseased slides on one or more computers. It is made up of two steps. The first approach requires using specialized equipment (a scanner) to digitize glass slides, which results in a large representative digital image (a "digital slide"). The second method involves viewing and/or analyzing these massive digital data using specialist software (e.g., virtual slide viewer). It's becoming more popular in both clinical and research settings. It allows pathologists to remote access the entire slide.

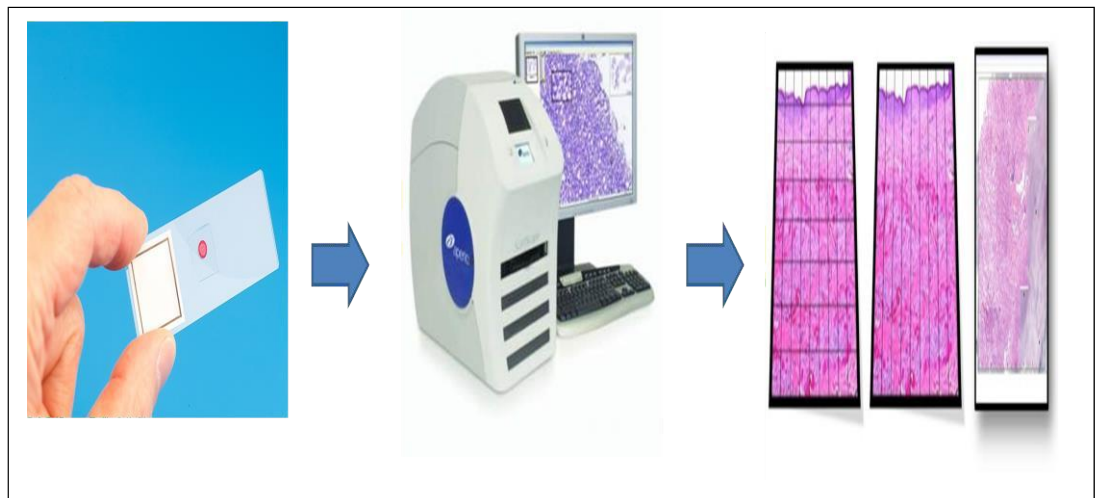


Figure 6. Whole Slide Imaging

- **Telepathology** is the technique of using digital transmission of pathological data to aid in medical diagnosis. It makes use of telecommunications technology to make image-rich pathology data transfer across remote places easier for education, research and diagnosis. Telepathology system consists of a digital imaging workstation for acquiring images, a telecommunications network for transmitting images, and a monitor or screen for viewing digital images remotely.



Figure 7. Telepathology

6.1.2 Market Segmentation by Application

In the second segment, the market is segmented on the basis of application which includes academic research, diagnosis and drug discovery and development,

- **Drug discovery and development** includes research both internal and external, drug metabolism and its formulation, testing and clinical trials.
- **Academic research** digital pathology is used for morphological studies of tumors and biomarker profiling within the research institutes.
- **Diagnosis** digital pathology is used for diagnosis of chronic diseases which gives accurate and fast results thus saving time and cost for the other test experiments.

6.1.3 Market Segmentation by Region

In the third segment, the market has been split by regions:

The **North American** regional segmentation includes the markets of the U.S. and Canada.

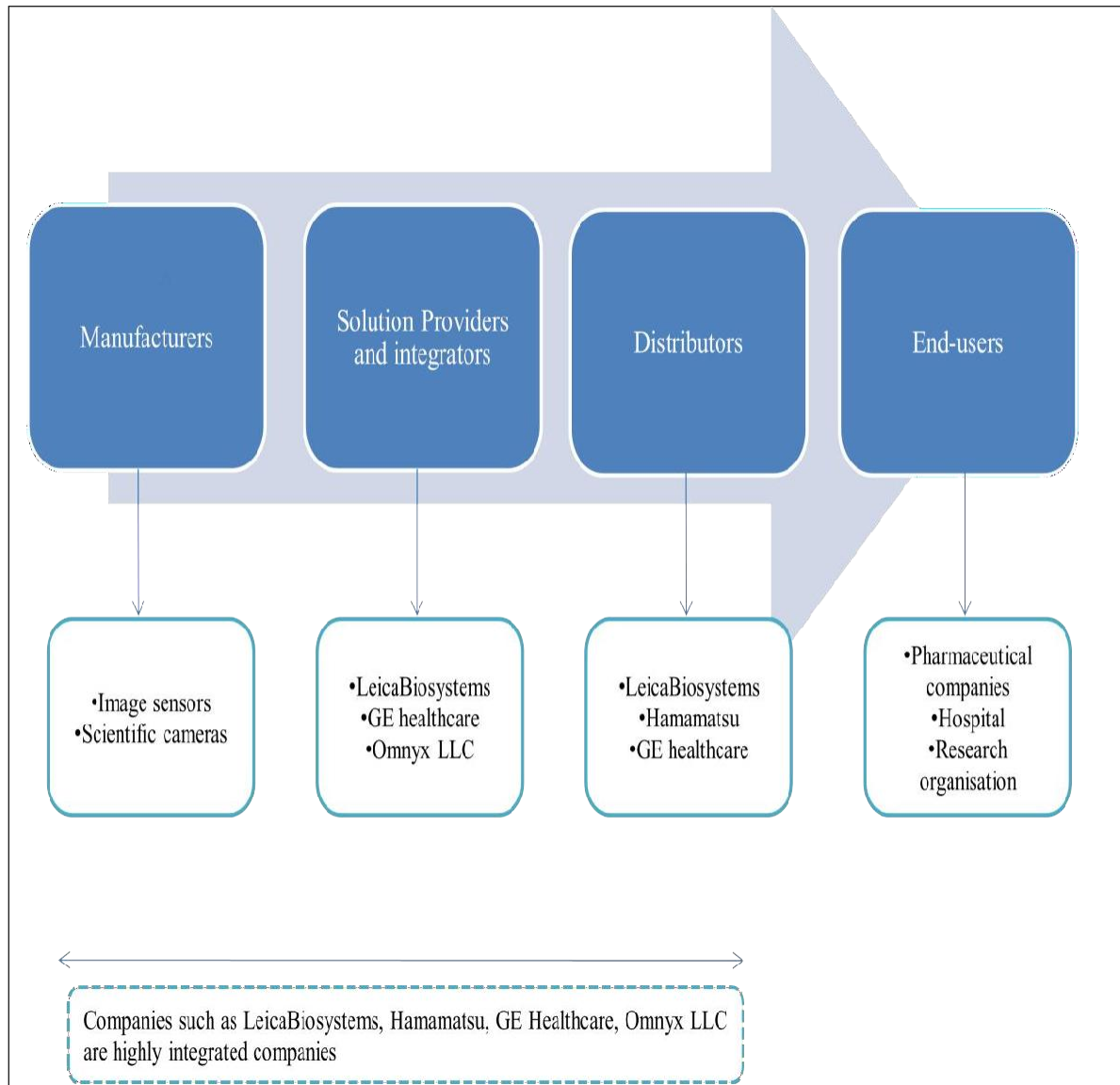
The **European** regional segmentation includes the markets of the UK and Germany.

The **Asia Pacific** regional segment includes the markets of China and Japan.

Latin American geographical segmentation includes the markets of Brazil and Mexico

Middle Eastern and African geographical segmentation includes the markets of South Africa.

6.2 Digital pathology-Value Chain Analysis



(Source: data collected by researcher after studying various report)

Figure 8. Digital Pathology - Value Chain Analysis

Interpretation: -

The Value chain for digital pathology market consists of Manufacturers, solution providers, distributors and End- users. Technological advancements in the field of pathology mainly to reduce time in the diagnosis of patients and to get accurate results are the factors because of which digital pathology is gaining acceptance.

Solution provider and integrators, combines the hardware and software to provide a system to the end user through third party distributors. Companies such as Leica Biosystems, Hamamatsu and others act as the third party between solution provider and End-users. There are some companies like Leica Biosystems, Omnyx LLC which are highly integrated. Digital pathology serves pharmaceutical companies, research organization, hospitals and others.

6.3 Digital Pathology - Drivers and Restraints

6.3.1 Market Driver Analysis

6.3.1.1 Increasing prevalence of chronic conditions

There has been an increase in the number of cancer cases, which has resulted in longer diagnosis and treatment wait times. At the same time, the sophisticated diagnosis and treatment methods being adopted are considerably increasing the survival rate among cancer patients, and have been doing so for the past few decades. This development as well as the growing demand for cancer care is stressing healthcare budgets to a point that is no longer sustainable. Moreover, patients are becoming more demanding, increasingly seeking for fast along with high-quality care.

6.3.1.2 Need for early diagnosis to reduce time and healthcare expenditure

Due to increases in the accuracy of cancer diagnoses among non-subspecialty pathologists, the installation of a computerized pathology system reduced treatment expenses. We also see that many countries are incorporating new national legislation to reduce waiting times. One example is the standardized cancer pathways in Sweden, where waiting times for five common cancers have been regulated since 2015 and an additional 14 cancer types during 2016. Both these trends challenge healthcare providers to improve the quality and efficiency of their cancer care.

6.3.2 Market Restraints Analysis

6.3.2.1 High initial cost of implementation

Digital pathology provides up-gradation in interpretive accuracy and workflow. Even though currently digital pathology is commonly used for education and research, its clinical use has been limited to niche applications such as remote opinion consultations and frozen sections. This is mainly owing to the regulatory barrier but also a fear of data supporting a positive economic cost-benefit.

6.3.2.2 Availability of cheaper conventional pathology processes

When compared with the digital pathology, diagnosis using a microscope is simple and highly cost effective. Digital pathology requires considerable significant costs for scanning and viewing equipment, as well as software and ongoing maintenance costs.

6.4 Market Dynamics – Digital Pathology

Technology trends • Shift from conventional microscopy to digital imaging that provide high-resolution scanning of tissue slides and derived technologies, including automatic computational and digitization processing of whole microscopic slides. • Emerging imaging software and slide scanner, thus improving quality of images.	Regulatory trends • In U.S., technology manufactured for digital pathology (i.e. scanners, software) are considered medical devices. They are regulated by the U.S Food and Drug Administration (FDA). • The Centers for Medicare & Medicaid Services (CMS) regulates all Laboratory testing performed on humans in the U.S. through the Clinical Laboratory improvement Amendments (CLIA).
Supplier/Vendor trends • Vendors reported functionality and better support as the top two things LIS (Laboratory Information system) vendors can do to retain contracts with provider. In addition, lower cost, more upgrades along with user-friendly system were among the important considerations for keeping contracts as said by provider. • LIS vendors are integrating their software with digital image management (pathology PACS) software to improve their competitive advantage.	Buyer's trends • Increased focus on improving workflow efficiency along with faster for diagnosis of chronic diseases is a surging its market growth. • Digital pathology provides accurate and faster detection and diagnosis of chronic diseases. It also reduces cost by omitting the requirement of FISH tests thus saving time, which causes inclination of the users towards this technology.

Source: data collected by researcher after studying various reports)

Figure 9. Digital Pathology Market Dynamics

Interpretation: -

Technological advancements in digital pathology system are one of the factors contributing to the market growth. Robotic light microscopy. Digital photography, computerization, and numerous fiber optic connectivity are all helping to drive the industry forward. WSI is one such approach that has a number of advantages over traditional light microscopes and is predicted to generate profitable chances in this market.

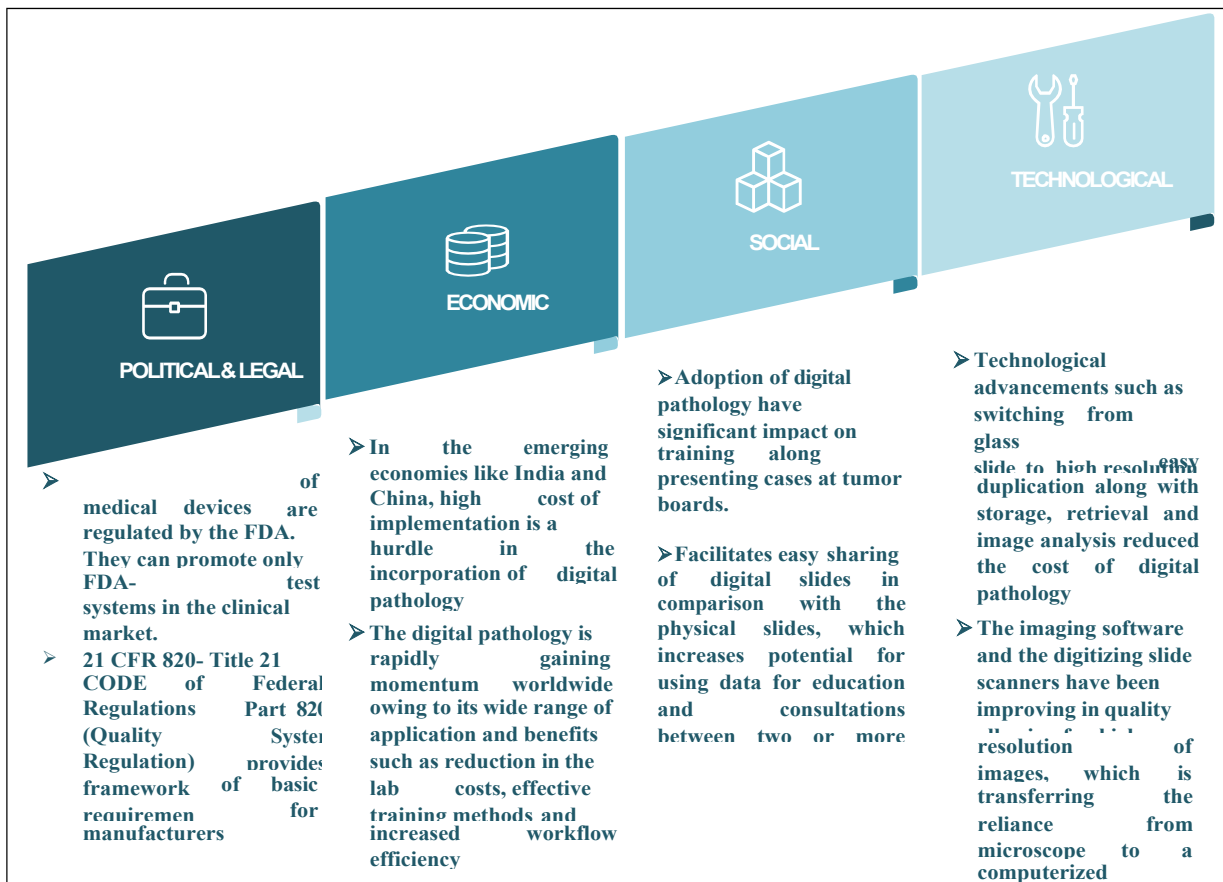
6.4.1 Porter's Analysis:

Threat of new entrants	Low	Threat of new entrants is expected to be low. As Large capital costs is required in the implementation of the system which acts as a barrier to enter the market. In addition, a strong marketing medium along with extensive distributor network also acts as a barrier for new entrants. However, the market is saturated with large number of existing industry participants. New entrants can collaborate with suppliers and distributors to gain market penetration.
Threat of substitutes	Low	Threat of substitutes is expected to remain Low. As there can be no real substitutes for the product. The end user is left with no choice but to use the product itself with different features offer by different company or to use conventional pathology method which is cheaper method as well as time consuming.
Competitive rivalry	High	The competitive rivalry in the industry is high with leading players such as GE Healthcare Omynx LLC; Leica Biosystems, 3DHistech, Inc.; Definiens; Olympus Corporation; Philips Healthcare; Objective Pathology Services; Hamamatsu Photonics, Inc.; LigoLAB LLC; Ventana Medical Systems and others. The companies are constantly upgrading the technology and are adopting innovative approaches. The increasing competition has affected the sales and profit margins of these players.
Bargaining power of suppliers	Low	As there is increasing demand for digital pathology, large number of suppliers exists in the market. In addition, technological upgradation is also one of the factors which leads to the large number of suppliers in the market. So, the bargaining power of suppliers is expected to be low, as many suppliers are present in the market end users are likely to switch from one supplier to another for lower prices.
Bargaining power of buyers	Moderate	The bargaining power is expected to remain moderate. The number of buyers is limited in the market but the competition among them is high. This creates more demand for the product and as there are many players in the market bargaining power remains moderate.

(Source: data collected by researcher after studying various reports)

Figure 10. Digital Pathology Market - Porter's Analysis

6.4.2 Digital Pathology Market – PESTEL Analysis



(Source: data collected by researcher after studying various reports)

Figure 11. Digital Pathology Market - PEST Analysis

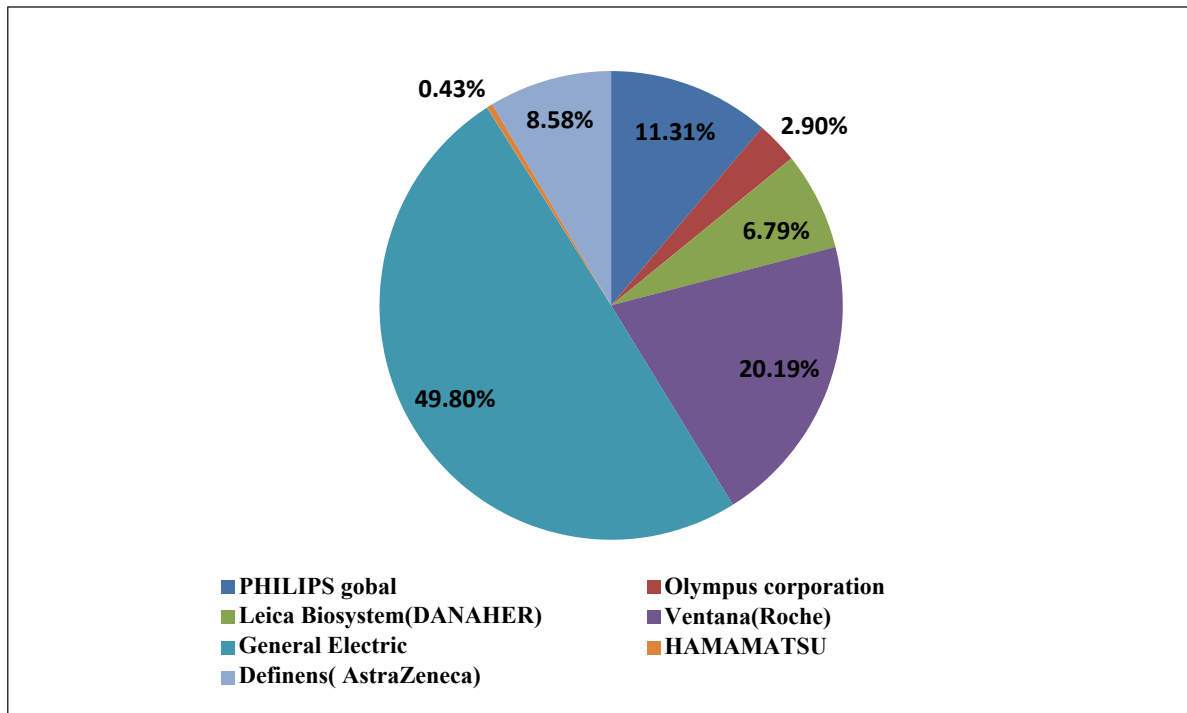
Interpretation: -

Technology plays a critical part in the market's expansion. Advancements in the pathology/technology are the important considerations for the growth in the digital pathology market. In addition, digital pathology saves time by elimination of various test and improvements in service delivery boost the market growth.

The market is affected by certain regulations which need to be approved by FDA. Only the CLIA and CAP rules should be considered while implementing digital pathology in a clinical laboratory. To be licensed to operate, clinical laboratories must meet CLIA requirements.

6.5 Competitive Analysis

Olympus Corporation, Objective Pathology Services, Leica Biosystems, GE Healthcare, Philips Healthcare, Hamamatsu Photonics, Inc., MicroSkan Technologies, LigoLab LLC, and Ventana Medical Systems, Inc., are among the leading players in the digital pathology market.



(Source: data collected by researcher after studying various reports)

Figure 12. Competitive Analysis

Interpretation: -

General Electric had a largest share of 49.8%, followed by Ventana and Philips global with 20.19% and 11.31% respectively. To increase profits, these companies are progressively engaging in new product development, comprehensive collaboration initiatives, and mergers and acquisitions. For example, In April 2020, Philips announced that the FDA has granted a waiver for the use of customer monitors with the company's IntelliSite Pathology Solution in the house during an emergency. Pathologists can now see entire slide images from home and diagnose histology cases faster thanks to a

temporary exemption of limits on remote usage of digital pathology.

Royal Philips and Ventana Medical Systems are also important participants. In June 2016, Royal Philips, a Dutch company, purchased Irish PathXL, one of the major pathological, image-based analysis providers. The aim of this purchase was to create integrated technologies for use in biology, workflow solutions, image analytics and computational education.

Additionally, this acquisition aims to support the progressive shift of medical institutions around the world from traditional pathology systems to digitized pathology systems. As a result of the aforementioned acquisition, pathologists will be able to do high-throughput analysis of huge clinical imaging collections of varying nature and increase diagnosis quality, potentially allowing for the inclusion of new medicines to improve patient health outcomes.

7 Covid -19 Impact Analysis

- The current coronavirus pandemic, has resulted in a large no. of patients visiting hospitals on a daily basis. The number of pathological tests performed around the world has reduced as a result of the pandemic. Furthermore, the global lockdowns and limits imposed in 2020 have harmed demand for these solutions. In the current and future climates, digital pathology can help to protect healthcare services and pathology-based research.
- Virtual slides can be evaluated to avoid any delays in important patient treatment using work from home. There's no need for any further gear.
- Still images, such as those captured with a digital camera linked to an optical microscope and representing the pathologist's location of interest in a complete tissue section, can be displayed on a display device. This is how speedy interdepartmental consultation can be accomplished while maintaining social distance at work.
- As an emergency service to the pandemic, the Royal College of Pathologists in the United Kingdom has developed suggestions for providing remote digital pathology slides during times of acute service demand.
- The use of common consumer monitors in the Philips IntelliSite Pathology Solution at home has been authorized by the FDA.
- The FDA has awarded Leica Biosystems approval to commercialize its Aperio AT2 DX System in the United States for clinical diagnosis and remote diagnosis of coronavirus patients in an emergency situation, which is essentially the same as Philips' technology.

8 Observations / Findings

- Commercial off-the-shelf components, such as pathology monitors and complicated software systems, are often used in digital pathology systems (both require proper configuration).
- The analysis of the digital pathology market demonstrates the importance of putting more emphasis on enhancing the effectiveness of the workflow and developing speedier diagnostic tools for chronic diseases. In 2020, the global digital pathology market was estimated to be worth USD 386.02 million.
- The quality of imaging software and digitizing slide scanners has been improving, allowing for better image resolution. Digital pathologists would be able to better assess tissue samples and get more accurate results by obtaining a better look at them.
- Patient electronic health records, as well as allowing consultations and referrals, are examples of information that can be shared to improve patient care.
- There are various factors which boost the market growth of digital pathology such as rising prevalence of chronic diseases, advancement in technology (digital imaging and computerization) and need for early diagnosis to reduce time and healthcare expenditure.
- High cost of implementation, availability of cheaper conventional pathology processes, shortage of skilled pathologist are the factors which hinders the market growth.
- North America region dominated the digital pathology market followed by Europe and Asia. The overall market share held by North America is 38.85%, by

Europe is 28.39% and by Asia is 28.17%.

- Due to increased awareness of the numerous potential benefits and the encouragement of digital pathology by Asian ministries of health to improve the quality of cancer detection, the Asian market is predicted to develop the fastest over the next several years.
- With digital pathology making its way into clinical laboratories, it's more important than ever for physicians and laboratory workers to understand regulatory requirements and how to best implement them in their facilities.
- Improvements in service delivery, patient safety, and communication, as well as decreased mistake rates, cheaper costs, and better and more effective data utilization, are all possible benefits of digital pathology.

9 Limitations

- This research project provides the secondary research information about the market for the past 2 years in terms of demand, shares and sales in USD.
- This project report i.e., major market dynamics, the technological trends and end-use markets were evaluated based on the historic estimations, and not on the forecast.
- Data is been extracted and collected under various web-based reports, projects, websites, so there is a possibility that the data would not be authentic to justify the analysis and to analyze the long-term considerations.

Assumptions made in while drafting the digital market report

- The estimations for the digital pathology market were made from the demand side and consumer's perspective.
- The regional or any other inflation has not been taken into account while the study.

10 Suggestions/ Recommendations

In this research project, secondary research has been conducted to suggest marketer with different strategies to enter or survival in the digital pathology market owing to the demand of digital pathology in various regions.

1. The marketer should concentrate on technologies, and understand and use the technology advancement for further growth of the company.
2. Understanding the rules and regulations and government policies in favor and unauthorized use of digital pathology.
3. Companies should integrate with the value chain that is manufacture the raw material itself, then device building and distribution, which will save the overall cost of the company involved in raw material procurement and distribution.
4. The digital pathology market is at the phase of enormous growth and owing to high awareness, there should be untapped market for new entrants and this is perfect time for new entrants to enter and invest in the market, hence opportunities can be capitalized.

11. Conclusion

Digital pathology and telepathology have evolved from an intriguing concept in the late 1990s to a viable and helpful tool in research and clinical pathology. The introduction of fluorescent slide scanners, multi spectral imaging technology, digital slide scanners, and computer horsepower propelled this transformation at first. As we progress into customized medicine, integrated systems with increasingly complex and functional software tools are being developed. These systems will become part of our diagnostic toolbox. By digitalizing microscopic analysis, digital imaging offers the possibility of incorporating primary picture features into high-dimensional genomic experiments. Digital pathology will likely open up new paths for computational analysis of specific disease tissues, transforming pathology practice.

In the end, digital pathology is simply another method of performing pathology, with the same regulatory constraints. It offers physicians and laboratory staff a regulatory overview and a reference framework to help them implement digital pathology in their clinical laboratories.

There's a disconnect between what manufacturers have to offer in terms of digital pathology systems, hardware, and software, and how a digital pathology solution should be used in a clinical context

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13. Market Share

North America Digital Pathology Market 2019

2020	2019	2020
Leica Biosystem(DANAHER)	5.68	6.3774
Olympus corporation	0.249896	2.496531
Ventana(Roche)	21.74416	22.80348
PHILIPS global	8	7.713
HAMAMATSU	36.26846	33.75903
Definens(AstraZeneca)	13.664	12.656
General Electric	65.2	63.8
Total	150.33	150

Europe Digital Pathology Market 2019-2020

2019	2020
Leica Biosystem(DANAHER)	0.8584
Olympus corporation	0.195223
ventana(Roche)	13.73506
PHILIPS global	2.802
HAMAMATSU	30.55799
Definens(AstraZeneca)	17.703
General Electric	32.8
Total	98.651673

Asia Pacific Digital Pathology Market 2019-

2020	2019	2020
Leica Biosystem(DANAHER)	2.2214	2.6638
Olympus corporation	0.300706	2.735009
Ventana(Roche)	9.987063	11.04018
PHILIPS global	4.611	4.749
HAMAMATSU	57.413	60.642
Definens(AstraZeneca)	6.219	6.489
General Electric	19.3	20.4
Total	100.052169	108.718989

RoW Digital Pathology Market 2019-2020

2019	2020
Leica Biosystem(DANAHER)	5.68
Olympus corporation	0.018846
Ventana(Roche)	1.410023
PHILIPS global	9
HAMAMATSU	0.3437426
Total	16.76

Region	2019	2020	Percentage
North America	150.33	150	38.85%
Europe	98.65167	109.5815	28.39%
Asia-Pacific	100.0522	108.719	28.17%
RoW	16.76	17.73	4.59%
Total	365.7938	386.0305	100%

Company	2019	2020	Percentage
PHILIPS global	27780.23	28,092.59	11.31%
Olympus corporation	6800.59	7155.5	2.90%
Leica Biosystem(DANAHER)	14,433.70	16,882.40	6.79%
Ventana(Roche)	52680.47	50148.313	20.19%
General Electric	117,386	123,693	49.80%
HAMAMATSU	1073.31	1083.63	0.43%
Definens(AstraZeneca)	23,641	21,319	8.58%
Total	243795.3	248,374.43	100%