

STUDY ON INDUSTRY OUTLOOK OF DIGITAL PATHOLOGY MARKET

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INTRODUCTION

- ❑ Digital pathology, also known as virtual microscopy, is defined as a dynamic, image-based system that allows pathology information to be acquired, managed, and interpreted from a digitized glass slide
- ❑ It 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
- ❑ 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.

RESEARCH OBJECTIVES



TO UNDERSTAND THE
CURRENT STATUS OF DIGITAL
PATHOLOGY MARKET
GLOBALLY.



TO STUDY THE MARKET
SEGMENTATION OF THE
DIGITAL PATHOLOGY MARKET
BY TECHNOLOGY,
APPLICATION, AND
GEOGRAPHY



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

RESEARCH METHODOLOGY

Study design :- Descriptive study

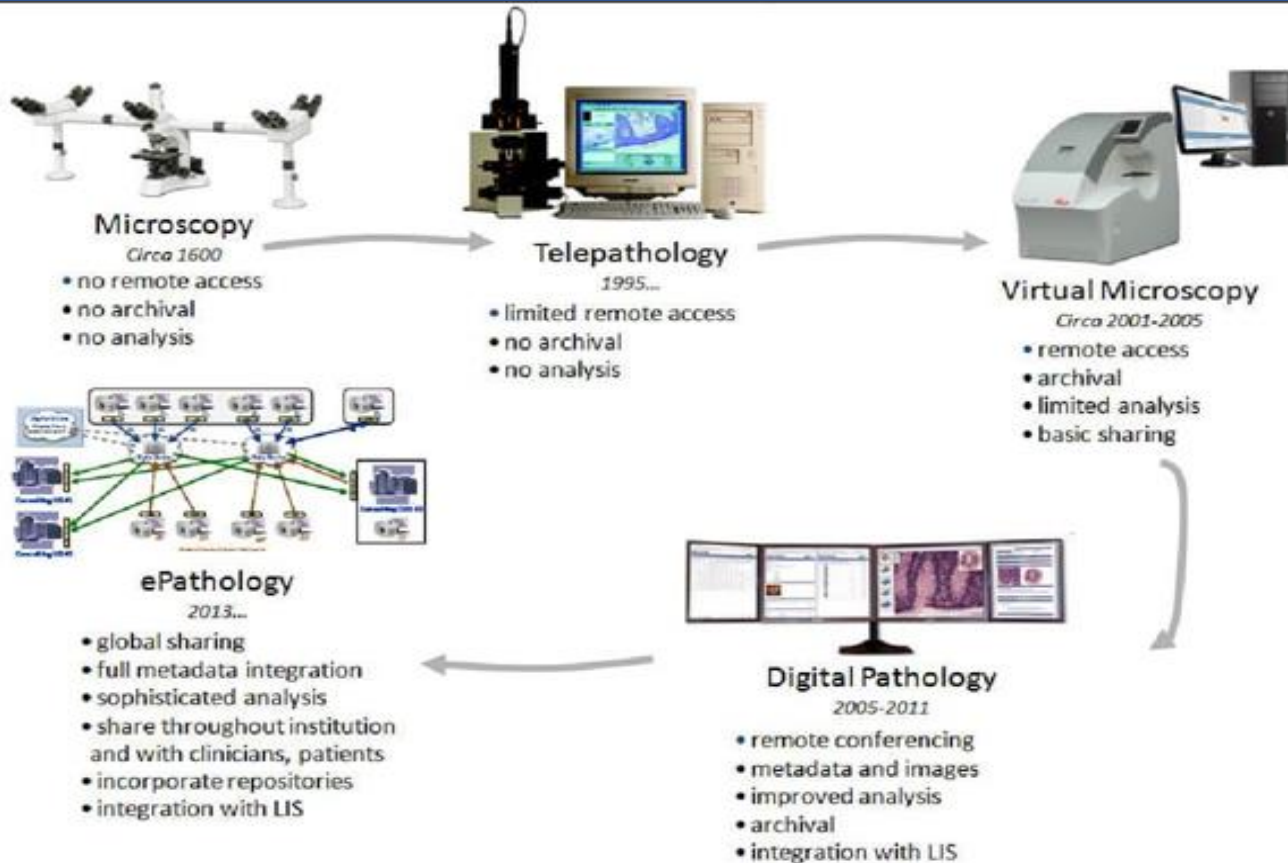


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graph TD; A[Study design :- Descriptive study] --> B[Data considered :- Market research reports, company websites, internet articles and online blogs, company annual reports and industry practices, websites.]; B --> C[Data is analyzed using statistical tool Microsoft Excel for organizing numerical data, calculation of percentage and preparing pie-charts.];
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LITERATURE REVIEW



Evolution of digital pathology

- In 1968, the first pathology slides were digitized as black and white digital images and transported from Logan Airport in Boston to Massachusetts general hospitals.
- It was a significant step toward appreciating the benefits of such technology, such as the potential to convert pathology slides into digital images that could subsequently be transferred over long distances (Telepathology).

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

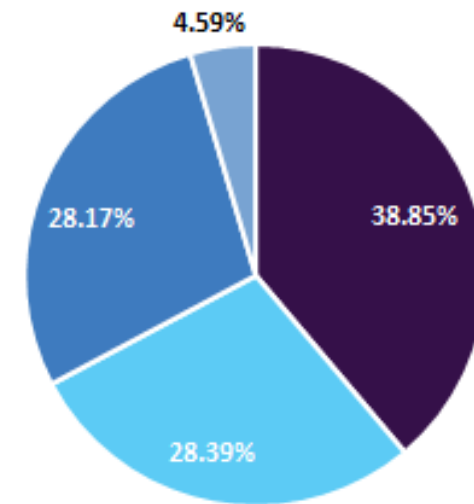
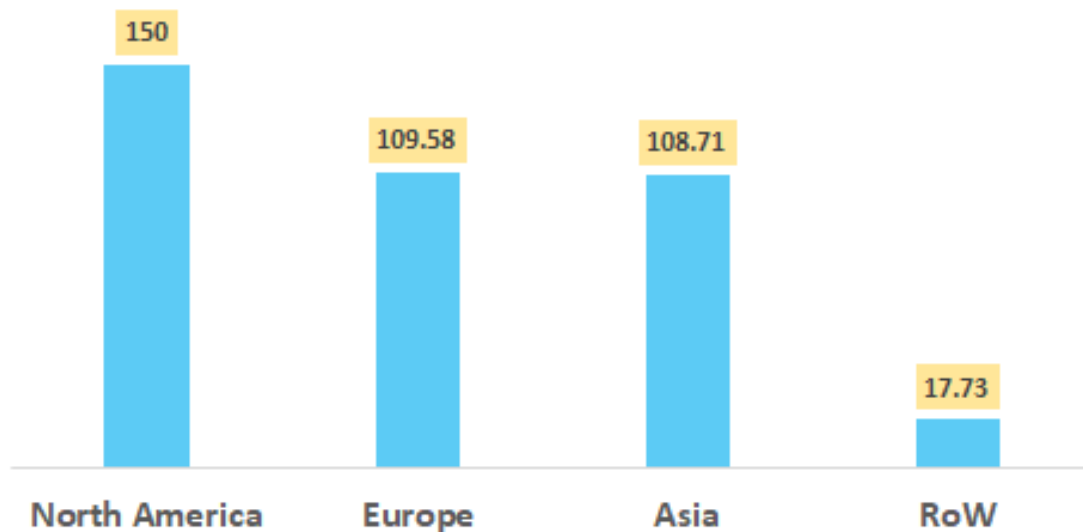
- The term telepathology was coined by Ronald S. Weinstein, M.D., an academic pathologist, in 1986
- Robotic telepathology was demonstrated utilizing color video via satellite between Texas and Washington, D.C. in 1986.
- Norway established a nationwide telepathology programme for frozen section services 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.

Digital Pathology Market : Global Analysis

- The global digital pathology market was estimated to be worth USD 386.02 million in 2020.
- 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, growing prevalence of cancer, investments in the medical field are increasing and the presence of undiscovered potential.

Global Digital Pathology Market 2020 (USD Millions)



■ North America ■ Europe ■ Asia ■ RoW

In North America the contributing factors include continuous R&D investments, efforts connected to the construction of technologically advanced systems, supporting government better adoption of digital photography, and the existence of major players in the region.

Market Drivers

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

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

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.

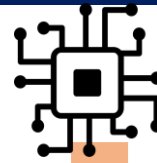
Availability of cheaper conventional pathology process

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

Market Restraints

MARKET SEGMENTATION

DIGITAL PATHOLOGY



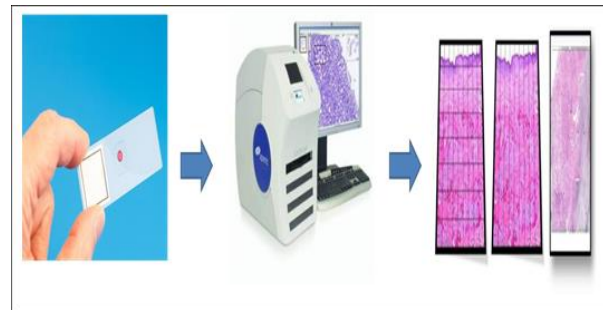
APPLICATION

- Drug discovery & development
- Academic Research
- Diagnosis



TECHNOLOGY

- Whole Slide Imaging
- Telepathology



Tele Pathology

Electronic transmission of computerized or digital images utilized for diagnostic consultation.



Types of Telepathology Systems
Static Image Based | Real Time Systems | Virtual Slides Systems

REGION

- North America
- Europe
- Asia pacific
- Latin america
- MEA

MARKET DYNAMICS

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.

P/L



Manufacturers of medical devices are regulated by the FDA. They can promote only FDA approved test system in the clinical market.

21 CFR 820-Title 21 Code of federal regulations part 820 Quality system regulations provides framework of basic requirement for manufacturers.

E



In the emerging economies like India and China, high cost of implementation is a major hurdle in the incorporation of digital pathology solutions.

The digital pathology is rapidly gaining momentum worldwide owing to its wide range of application & benefits such as reduction in the lab costs, effective training methods and increased work flow efficiency.

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Adoption of digital pathology have significant impact on education, training along with presenting cases at tumor boards.

Facilitates easy sharing of digital slides in comparison with the physical slides, which increases potential for using data for education and consultations between two or more experts.

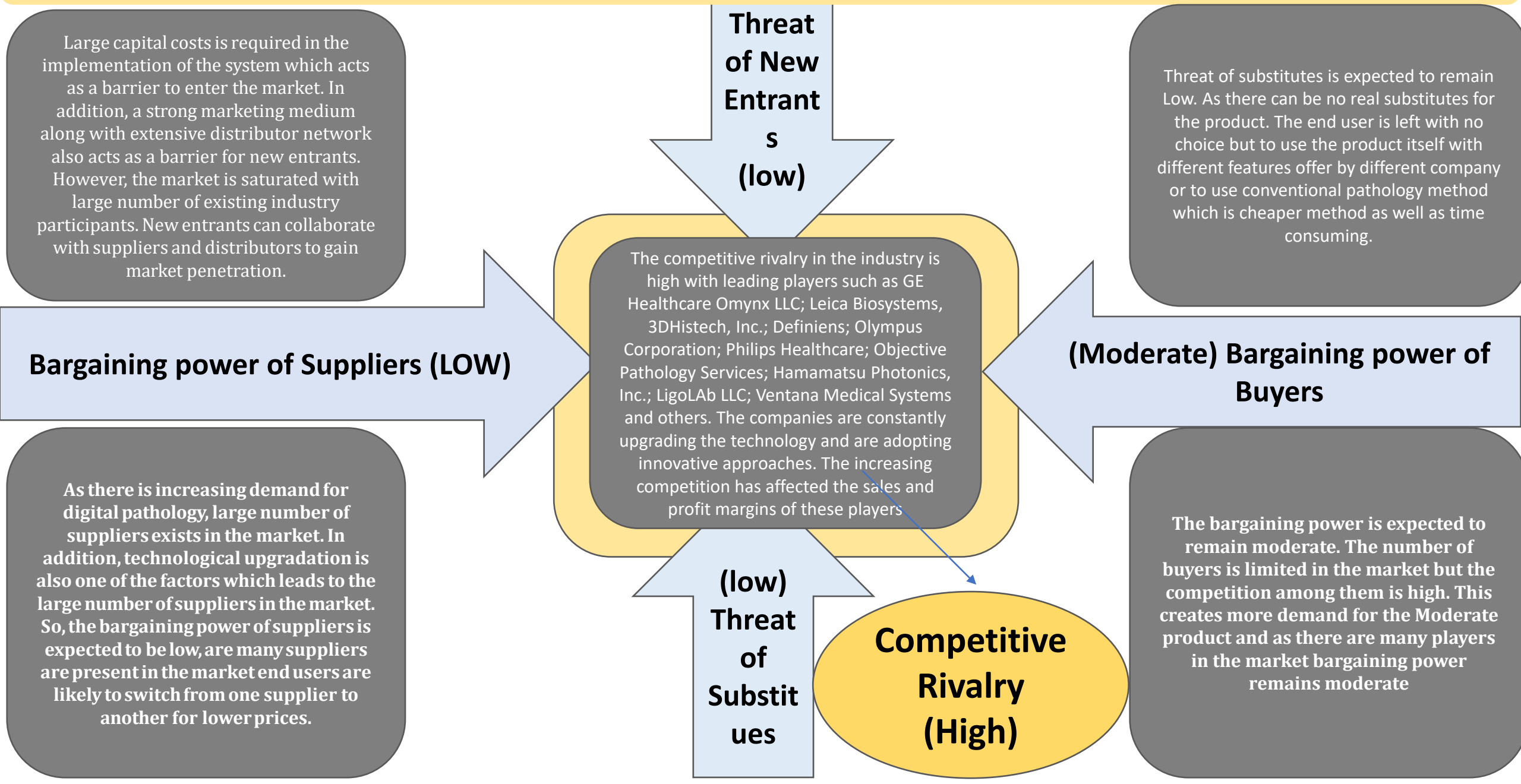
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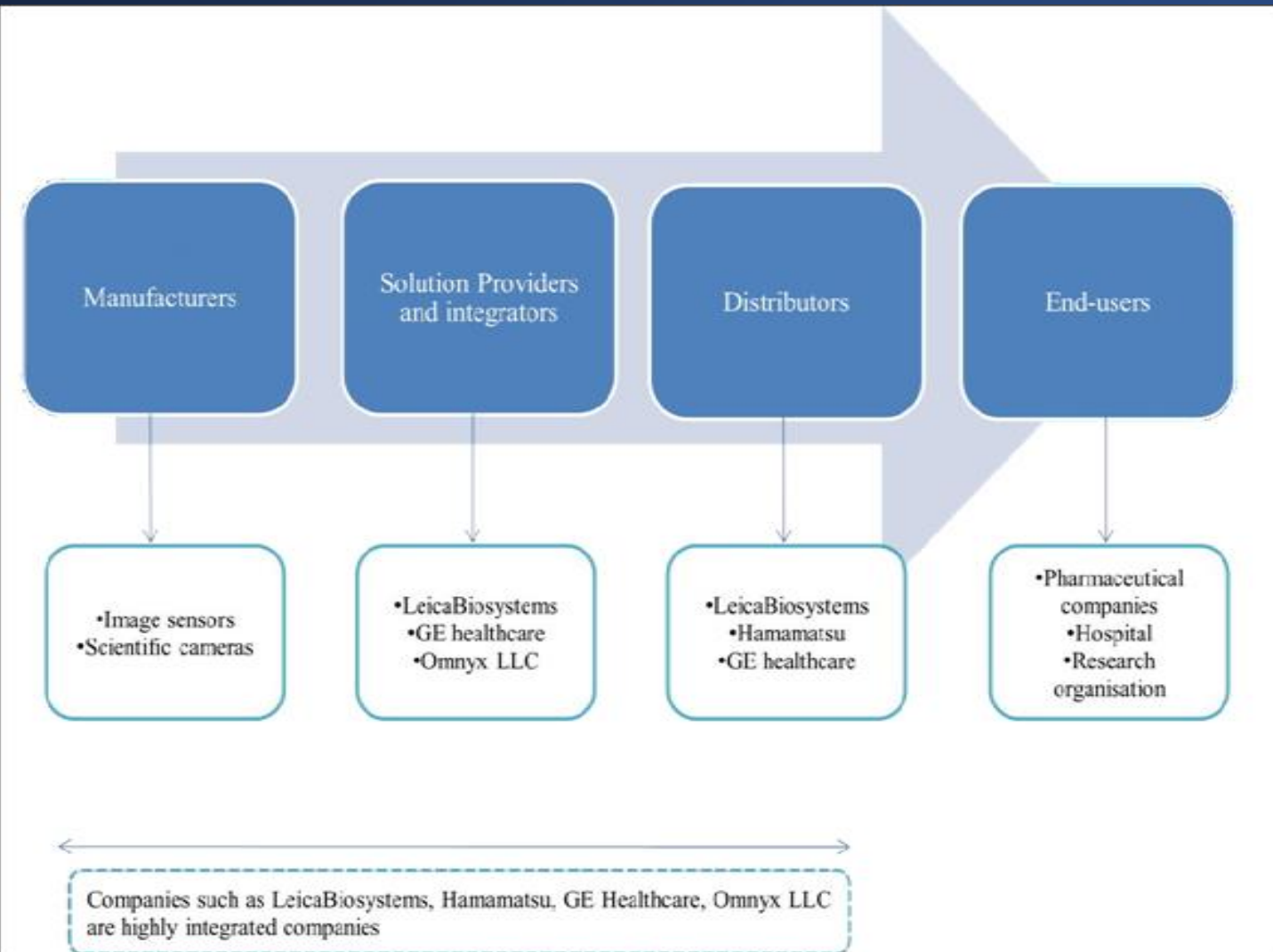
Technological advancements such as switching from glass slide to high resolution digital slide, easy duplication along with storage, retrieval and image analysis reduced the cost of digital pathology.

The imaging software and the digitizing slide scanners have been improving in quality allowing for higher resolution of images, which is transferring the reliance from microscope to a computerized image

PORTER'S ANALYSIS



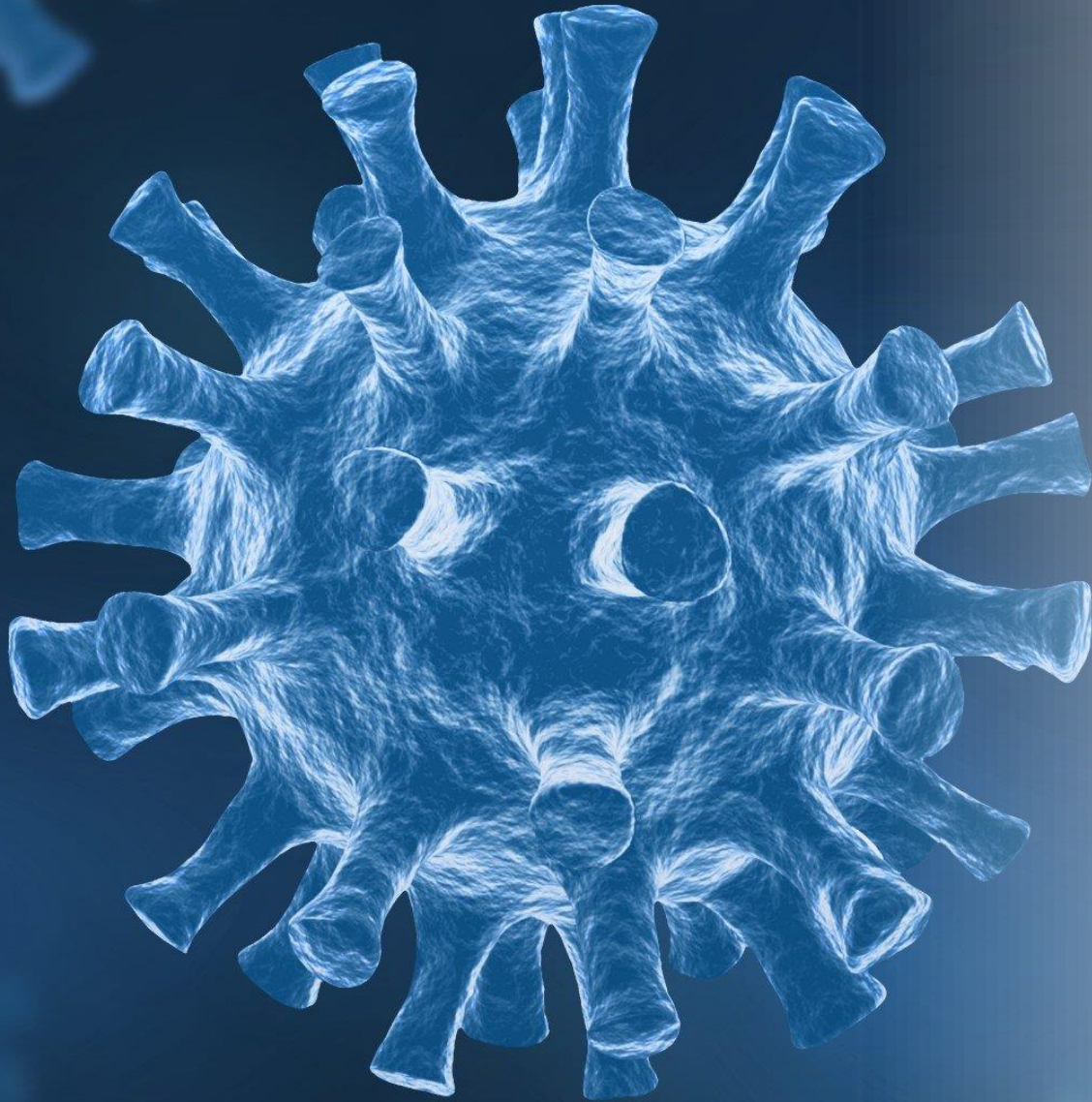
VALUE CHAIN ANALYSIS



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.

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.
- 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.
- 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

Competitive Analysis



GE Healthcare

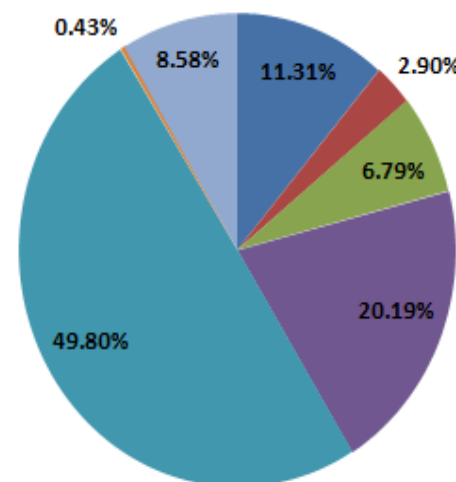
LigoLab
INFORMATION SYSTEM

BIO SYSTEMS

mikrOscan



PHILIPS
Healthcare



■ PHILIPS gobal
■ Leica Biosystem(DANAHER)
■ General Electric
■ Definens(AstraZeneca)
■ Olympus corporation
■ Ventana(Roche)
■ HAMAMATSU

In April 2020, Philips announced that the FDA has granted a waiver for the use of customer monitors with the company's Intelli-Site 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.

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.

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.

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.

Suggestions/ Recommendations

- The marketer should concentrate on technologies, and understand and use the technology advancement for further growth of the company
- Understanding the rules and regulations and government policies in favor and unauthorized use of digital pathology.
- 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.
- 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.

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 is a new industry & technology that is finding its way into clinical laboratories. CLIA, CAP, and the FDA, for example, provide very little guidance. In order to assist clinical laboratories in achieving regulatory criteria, manufacturers must still comprehend what it means to supply instruments to a clinical laboratory.
- 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 is a discrepancy between what manufacturers offer in terms of digital pathology systems, hardware, and software, and how a digital pathology solution should be implemented in a clinical setting.

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