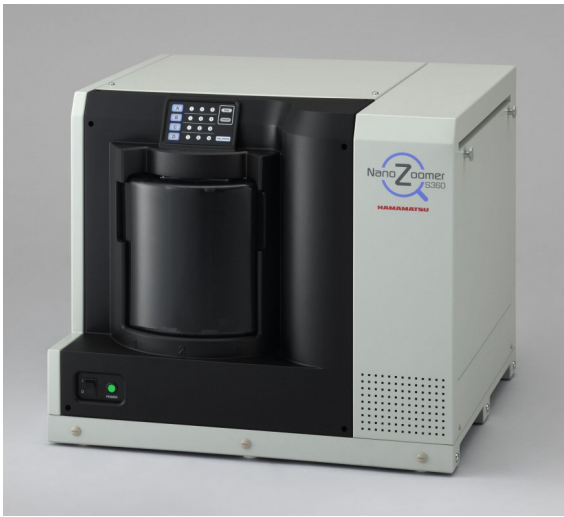# The fast track to healthy digital pathology

When you are under pressure to introduce digital pathology urgently, how can you ensure your deployment is a success?

Executive Summary

Pathology – the science of analyzing human cells, tissues and bodily fluids to diagnose disease – is a vitally important part of the patient care process. It has been estimated that 95% of clinical pathways rely on patients having pathology tests,1 but pathology services around the world are in crisis.

There is a global shortage of trained pathologists, and a high proportion of the scientists working in this field are approaching retirement age. At the same time, critical illnesses like cancer are becoming ever more prevalent, increasing the demand for pathology services. Unfortunately, the COVID-19 pandemic has placed an unwelcome additional strain on pathology teams and highlighted the need for more flexible and collaborative working from any location.

Digital pathology addresses these challenges by enabling limited teams of pathologists to work more efficiently from any location and deliver faster diagnoses for patients. Pathologists review high resolution images of tissue or cell samples on digital screens and can share these images easily to get faster second opinions. They can also work more closely with colleagues and peers across multiple hospitals to deliver cost effective, consolidated services.

Research has shown that healthcare organizations are not only planning to invest in digital pathology – they are planning to do so very soon, within the next two years. In the UK, the migration to digital pathology is being driven by the need to reduce costs and standardize services in the NHS. Hospitals throughout England are consolidating their pathology services and using digital pathology as the means of delivering significant reforms. In the USA meanwhile, proposed changes to Food and Drug Administration (FDA) procurement regulations are expected to dramatically accelerate the adoption of digital pathology image viewing and management software.

While digital pathology is undoubtedly urgently needed and in high demand, it must be deployed with care. There are a number of key challenges that come with deploying such transformational new technologies. CTOs, CIOs and IT Directors in hospitals and healthcare organizations will need to take steps to ensure that their new pathology systems deliver the 100% availability that is critical for such a pivotal patient service, while also ensuring that patient data can be shared securely within and between healthcare providers.

Organizations will need to be able to handle exceptionally high volumes of large image files, integrate legacy systems and, at the same time, consider how to incorporate future developments in areas such as artificial intelligence (AI).

1 The Royal College of Pathologists. Pathology Facts and Figures [Internet]. Available from: https://www.rcpath.org/discover-pathology/news/fact-sheets/pathology-facts-and-figures-.html (accessed 21 March 2021)

> *Pathologists can view and share samples more quickly and easily, which can significantly speed up diagnoses, facilitate faster referrals between hospitals and lead to better health outcomes for patients.*

Installing a load balancer to manage the traffic and data associated with a digital pathology solution is an effective way to address these challenges. Load balancers improve the reliability of pathology systems, enable remote working and help to prevent the loss of patient data. Able to handle vast quantities of large image files, they can be used to simplify the integration of legacy solutions like aging laboratory information management systems (LIMS) and pave the way for AI in the future.

Load balancers can be inexpensive to acquire and simple to manage, so won't be an added burden for in-house IT teams that are already over-stretched. Most digital pathology vendors do not supply a load balancer with their solutions, but load balancing is a vital component in any digital pathology system. Healthcare organizations and hospitals should, therefore, seek advice from a load balancer vendor with experience of medical imaging and get on the fast track to healthy digital pathology.

What is digital pathology?

Digital pathology is not a product, but an approach. Broadly speaking, it is the end-to-end process for: capturing high quality digital images of cell samples; analyzing those digital images to diagnose disease; sharing the images with other pathologists or healthcare professionals; and storing them, in case they are needed for reference again in the future. The Digital Pathology Association, for example, describes digital pathology as, "A dynamic, image-based environment that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide."[2]

Digital pathology will never be an entirely digital process, because a glass slide will always be needed to hold the original cell, tissue or fluid sample.However, once a digital image has been taken of the sample on the glass slide – known as a whole-slide image (WSI) – the remainder of the pathology process becomes much more efficient. Pathologists can view and share samples more quickly and easily, which can significantly speed up diagnoses, facilitate faster referrals between hospitals and lead to better health outcomes for patients.

Critically, pathologists don't need to be in the same location as the patient or the sample and can therefore diagnose disease from any hospital, clinic or at home, provided he or she has a high definition screen. As Dr. Bas Hulsken puts it, in his 2018 whitepaper on Seamless Computational Pathology, "Digital pathology is unchaining pathologists from their (physical) labs."[3] This ability to conduct pathology at a distance is often referred to as 'telepathology' and has several advantages. In particular, it allows hospitals to share pathology services, reducing costs and improving their access to specialists.

Beyond patient care, digital pathology paves the way for digital images of samples to be made more readily available for educational purposes, for the training of future pathologists and medical students.

2 Digital Pathology Association. About Digital Pathology [Internet]. Available from: https://digitalpathologyassociation.org/about-digital-pathology (accessed 16 March 2021)
3 Hulsken, B. Seamless Computational Pathology. Philips White Paper 2018. Available from:
https://www.philips.com/c-dam/b2bhc/master/sites/pathology/resources/white-papers/seamless-computational-pathology.pdf (accessed 16 March 2021)

Likewise, digital pathology will make it easier for samples to be shared for research purposes, helping to improve research into critical illnesses and accelerate the discovery of new treatments.

> 👍 **Benefits summary**
>
> ## Digital Pathology
>
> - Speeds up diagnoses for patients
> - Enables faster referrals and second opinions
> - Gives pathologists the flexibility to work from more locations
> - Reduces costs by facilitating shared pathology services
> - Improves the availability of samples for research and education

Is digital pathology viable now?

It most certainly is. In the past, the widespread adoption of digital pathology was hampered by the high cost of scanners and the low resolution of digital images. Now, however, technology costs are falling rapidly and high quality digital images can be captured with exceptional detail, enabling pathologists to identify microscopic changes in individual cells. Consequently, the digital pathology market is expected to grow at a compound annual growth rate of 14.52% during the period 2019 to 2024.[4]

One way to measure current levels of interest in digital pathology is to look at demand for whole-slide scanners, a key technology component required for digital pathology. In a market survey published in February 2021, 56% of the lab directors, pathologists and other professionals questioned indicated that they planned to invest in a new whole-slide scanner for clinical diagnoses.

Most significantly, 63% of these respondents planned to make this investment soon, within the next 1-2 years.[5] This shows that organizations not only consider digital pathology to be viable; they consider it to be a priority.

4 Digital Pathology Market by Product and Geography - Forecast and Analysis 2020-2024. Technavio 2020. Available from: https://www.technavio.com/report/digital-pathology-market-size-industry-analysis (accessed 16 March 2021)

5 Digital Pathology: At The Tipping Point. Hamamatsu Market Study 2021. Available from: https://www.hamamatsu.com/sp/sys/dl_documents/Hamamatsu_MarketStudy_202102.pdf (accessed 15 March 2021)

> *In the UK, a 2017 survey carried out by the Royal College of Pathologists found that only 3% of histopathology departments in the UK had enough staff to meet clinical demands.*

Why is digital pathology needed urgently?

There are several reasons why healthcare organizations need to deploy digital pathology quickly.

Escalating shortage of skilled pathologists

Firstly, there is a critical and escalating shortage of skilled pathologists globally. In the UK, a 2017 survey carried out by the Royal College of Pathologists found that only 3% of histopathology departments in the UK had enough staff to meet clinical demands.[6] Meanwhile, an academic study discovered that the number of active pathologists in the USA decreased by 17.53% between 2007 and 2017.[7] It is widely recognized that more pathologists are retiring than are entering the field, so digital pathology is needed to enable the world's limited pool of expert pathologists to work more efficiently.

Growing demand for pathology services

While skilled pathologists are in short supply globally, demand for pathology services is increasing – partly due to the aging population and partly due to the rising prevalence of serious illnesses. Worldwide, the proportion of people aged 60 or above is expected to rise from around 11% in 2011 to 22% by 2050.[8] Cancer is just one of the many illnesses that depend on pathology, but cancer incident rates alone are projected to increase by 61.7% between 2018 and 2040.[9]

Urgent need for flexible working

Finally, the global COVID-19 pandemic has created an urgent need for more flexible working. The challenges of social distancing, in particular, have demonstrated how important it is for pathologists to be able to work and collaborate from home or alternate locations. Quoted in the Hamamatsu Market Study, one eminent professor of pathology said, "The COVID-19 pandemic makes it essential to move samples around in a multi-institutional network and makes the ability to perform remote diagnoses valuable."[10] COVID-19 has irreversibly changed the world we live in and pathology needs to change with it.

6 Meeting pathology demand: Histopathology workforce census. Royal College of Pathologists 2018. Available from: https://www.rcpath.org/uploads/assets/952a934d-2ec3-48c9-a8e6e00fcdca700f/Meeting-Pathology-Demand-Histopathology-Workforce-Census-2018.pdf (accessed 16 March 2021)

7 Metter DM, Colgan TJ, Leung ST, Timmons CF, Park JY. Trends in the US and Canadian Pathologist Workforces From 2007 to 2017. JAMA Network Open 2019. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2734800 (accessed 16 March 2021)

8 Numbers & Statistics : all figures about aging — Silver Economy. Available from: http://www.silvereco.org/en/statistics/ (accessed 16 March 2021)

9 Worldwide cancer incidence statistics [Internet]. Cancer Research UK 2015. Available from:

https://www.cancerresearchuk.org/health-professional/cancer-statistics/worldwide-cancer/incidence (accessed 16 March 2021)

10 Michael Feldman, MD, Vice Chairman Clinical Services, Pathology and Laboratory Medicine at the University of Pennsylvania School of Medicine; Professor of Pathology and Laboratory Medicine at the Perelman School of Medicine at the Hospital of the University of Pennsylvania; and Director, Office of Pathology Informatics. Cited in Digital Pathology: At The Tipping Point. Hamamatsu Market Study 2021. Available from: https://www.hamamatsu.com/sp/sys/dl_documents/Hamamatsu_MarketStudy_202102.pdf (accessed 15 March 2021)

Why is now the best time to adopt digital pathology?

In both the UK and the USA, there are significant factors that are accelerating the adoption of digital pathology.

The necessity for consolidation

In England, NHS Improvement plans to consolidate pathology services in order to reduce costs and improve patient services. It aims to replace pathology services at 105 separate hospitals with 29 'hub and spoke' networks, in which one primary center supports the pathology services of other nearby hospitals. This huge program of reform was launched following the publication of a report by Lord Carter of Coles, which identified "unwarranted variation" in pathology services within England.[11] Digital pathology is seen as being the best way to achieve a more standardized approach to pathology across the NHS and deliver the more collaborative pathology process needed to ensure the success of the 'hub and spoke' model. Ultimately NHS England aims to save around £200 million through consolidation and digitization,[12] so there is understandable impatience for change.

> " *Ultimately NHS England aims to save around £200 million through consolidation and digitization, so there is understandable impatience for change.* "

The relaxation of regulations

On 15th January 2021, the US government announced its intention to permanently relax regulations surrounding the acquisition of digital pathology image viewing and management software.[13] Numerous 'regulatory flexibilities' were introduced previously, in 2020, by the FDA to expand access to certain medical supplies and devices needed to respond to the COVID-19 health emergency. Now the FDA plans to make these temporary flexibilities permanent and remove the need for section 510(k) premarket review. According to a survey conducted by Inspirata, a provider of cancer informatics solutions, 60% of the pathology community expects adoption of digital pathology to increase if these regulatory changes are confirmed – and 22% expects digital pathology adoption to increase rapidly.[14]

11 Operational productivity and performance in English NHS acute hospitals: Unwarranted variations – An independent report for the Department of Health by Lord Carter of Coles – February 2016. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf (accessed 28 January 2021)
12 Pathology networks: NHS Improvement [Internet]. Available from: https://improvement.nhs.uk/resources/pathology-networks/ (accessed 16 March 2021)
13 Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program [Internet]. Federal Register. 2021 Available from: https://www.federalregister.gov/documents/2021/01/15/2021-00787/making-permanent-regulatory-flexibilities-provided-during-the-covid-19-public-health-emergency-by (accessed 16 March 2021)
14 Mladenov E. The Community Has Spoken in Favor of Digital Pathology: Survey Results [Internet]. Available from: https://blog.inspirata.com/fda-survey-results (accessed 16 March)

What are the challenges of deploying digital pathology?

When deploying digital pathology solutions, some considerable issues need to be addressed in terms of IT performance, integration, scalability and data.

1. Ensuring 100% availability

Pathology is a critical healthcare service. In the UK, hospital labs typically run over 1 billion pathology tests each year,[15] while the estimated number of laboratory tests performed annually in the United States exceeds 13 billion[16]. Given just how important pathology is to patient care, and the sheer number of tests carried out, a top priority for hospital CIOs, CTOs and IT Directors will understandably be reliability.

2. Providing shared access to sensitive data

More and more hospitals and healthcare organizations in the UK and the USA are consolidating their pathology services to share resources, such as skilled pathologists, and save money. In the UK, this approach has been mandated by NHS Improvement and steps are already underway to reorganize over 100 separate pathology departments into 29 'hub and spoke' networks. While this consolidation makes sense from a financial perspective, it does create a technical challenge, as multiple teams, from different organizations need to be able to securely share the same data and systems.

3. Integrating legacy systems

Many pathology departments still rely on very old IT systems that are not standardized across the industry and do not integrate well with modern IT. There are even some systems still in use that are written using antiquated programming languages like COBOL. Consequently, one of the biggest headaches for hospital CTOs, CIOs and IT Directors is integration. When new digital pathology solutions are deployed, they will need to find a way to make these modern digital systems interoperate with their legacy solutions.

4. Managing exceptional data volumes

The need for vast amounts of data storage space is an inevitable side effect of digital pathology. A single 24-bit color WSI has an image size of 15GB, which would typically be compressed to around 300MB. A larger 3D image of a sample, comprising a stack of 10 images, could create a dataset of 3.75TB, which even when compressed would consume 75GB of storage space. Moreover, depending on country-specific regulations, some of these images may need to be saved for at least 12 years. CTOs, CIOs and IT Directors in healthcare organizations don't just need highly scalable storage solutions; they also need to consider how they are going to handle this immense volume of large image files to ensure that no images are lost.

15 The Royal College of Pathology. Pathology Facts and Figures [Internet]. Available from: https://www.rcpath.org/discover-pathology/news/fact-sheets/pathology-facts-and-figures-.html (accessed 21 March 2021)
16 AACC Policy Review. Laboratory Medicine: Advancing Quality in Patient Care [Internet]. Available from: https://www.aacc.org/advocacy-and-outreach/aacc-policy-reports/2015/laboratory-medicine-advancing-quality-in-patient-care (accessed 23 March 2021)

5. Future-proofing your investment

A huge amount of investment is being made in medical imaging globally, which means that new digital pathology solutions and methods could be just over the horizon. The British Government, for example, has pledged £50 million of further investment for the development of artificial intelligence (AI) solutions to improve diagnosis of disease. AI has the potential to accelerate the pathology process, as it can be used to count and grade individual cells in samples, in seconds. Healthcare organizations will want to be able to incorporate AI into their digital pathology services when they become available, so need to think ahead about how they can integrate new technologies easily.

How do load balancers address these challenges?

Load balancers are physical appliances or virtual solutions that manage the flow of traffic between applications and servers in a network. While load balancing capabilities are not generally embedded in most vendors' digital pathology products, load balancers are nonetheless an essential component of the wider IT environment needed to deliver digital pathology.

There are five key ways in which load balancers enable the optimum performance of digital pathology solutions.

They can be used to help:

1. Keep critical pathology services up and running

Load balancers share user traffic across all the available application servers and, where appropriate, across all available datacenters. If one server fails, for any reason, the load balancer will automatically direct the traffic to an alternate, functioning server, enabling pathologists to carry on working without interruption. Equally, load balancers can help provide remote access to digital pathology systems, making it possible for pathologists to work from home or a different hospital and collaborate more easily with colleagues elsewhere in the country to consider complex diagnoses.

> *Load balancing plays a role not only in facilitating connectivity between these replacement systems and digital pathology systems, but also in the stable migration of vast amounts of data from old to new systems.*

2. Facilitate multi-site collaboration

Load balancers play a key role in multi-site digital pathology deployment models, enabling data to be shared and replicated across several hospitals. They help to preserve the integrity of the data replicated across sites and prevent data loss. If an outage were to occur in a digital pathology system at one site, it is the load balancer that would step in and redirect user traffic to an alternative location, preventing any interruption in pathology services and delays in diagnoses that could put lives at risk.

3. Alleviate the challenges of system integration

Load balancers can be used to provide an interface between legacy solutions and state-of-the-art digital pathology solutions. For example, it has been estimated that nearly 30% laboratory information management systems (LIMS) are obsolete,[17] and the modern systems that replace them require hardware, infrastructure and connectivity to link them with modern digital pathology systems. Load balancing plays a role not only in facilitating connectivity between these replacement systems and digital pathology systems, but also in the stable migration of vast amounts of data from old to new systems.

4. Simplify data storage

Hospitals can use load balancers to manage the flow of data into and within data archives to avoid the kinds of failures that can lead to patient data loss. Load balancers can be used with a hospital's own vendor-neutral archive (VNA), a data archive supplied by a vendor or a public cloud, such as Azure or Amazon Cloud. Over time, hospitals are likely to adopt hybrid approaches to image archiving that include on-premise data archives and cloud-based systems, and load balancers can facilitate this model, by directing high volumes of exceptionally large images to the most suitable servers, based on performance and availability.

5. Open the door to artificial intelligence

In order for AI to work, it needs to receive a lot of data, fast. This means extracting large numbers of image files from archives and feeding them to the AI application in a tiny fraction of a second. Load balancers can perform this data transfer, integrating the two (or more) systems, ensuring that the AI can operate with consistently high performance and high availability. With the current shortage of trained pathologists (and a large proportion of the workforce approaching retirement), any technology that speeds up the pathology process will be welcome.

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17 The Royal College of Pathologists. IT and Laboratory Information Management Systems (LIMS) [Internet]. Available from: https://www.rcpath.org/discover-pathology/public-affairs/it-and-laboratory-information-management-systems-lims.html (accessed 23 March 2021).

What should you look for in a load balancer vendor?

Digital pathology solutions providers sometimes recommend a preferred load balancer to complement their solutions, but organizations may need to specify and source their own. The following tips may help.

Experience in healthcare

This is often overlooked but vitally important. Healthcare organizations are 24/7 businesses that handle incredibly sensitive data, in a highly regulated environment in which lives are literally at stake. The load balancer vendor will need to understand the entire technical environment, not just the digital pathology application. Load balancing is unique in that it acts as the conduit for data between applications, so the vendor has to understand what goes on beyond the digital pathology solution. There has to be an understanding of: how clients (either the digital scanners generating images, or clinicians accessing those images) access applications and the workloads they generate; how the application behaves; and how to monitor the solution to ensure availability and performance.

Vendor validation

The chosen digital pathology solution provider will want all of its customers to have a reliable load balancer to ensure the optimum performance of their digital pathology environments. It is likely, therefore, that this vendor will have previously evaluated different brands of load balancer to assess their suitability. It is best to seek the vendor's advice and consider load balancers that have been tested, validated and endorsed by the supplier of the digital pathology solution or one of its trusted partners.
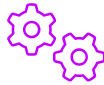
Dedicated load balancing

Healthcare organizations will almost inevitably already have a load balancer and many will have large load balancer platforms serving multiple applications in the hospital network. While it can be tempting to just add digital pathology to this existing load balancer, this can be a risky approach. Digital pathology is such a mission-critical application that it warrants a dedicated load balancer.

This sounds like a more expensive option but in the long run it isn't. Organizations can acquire intelligent load balancing solutions – dedicated for digital pathology – for a low cost that are easier to configure than large load balancer platforms, can be supported by in-house teams and therefore have a lower total cost of ownership.

Simple management

Finally, the deployment, management and maintenance of the load balancer must be simple for hospital IT staff, an already over-stretched resource. Digital pathology doesn't need a highly sophisticated load balancer with complex settings and rulesets that are difficult to master; it just needs a load balancer that works. A load balancer that offers a standardized deployment model for the chosen digital pathology solution, that has been tested with this application and that has a web interface for easy day-to-day management, can be the simplest – and best – option.

About Loadbalancer.org

Loadbalancer.org's mission is to ensure that its clients' businesses are never interrupted. The load balancer experts ask the right questions to get to the heart of what matters, bringing a depth of understanding to each deployment. Experience enables Loadbalancer.org engineers to design less complex, unbreakable solutions - and to provide exceptional personalized support.