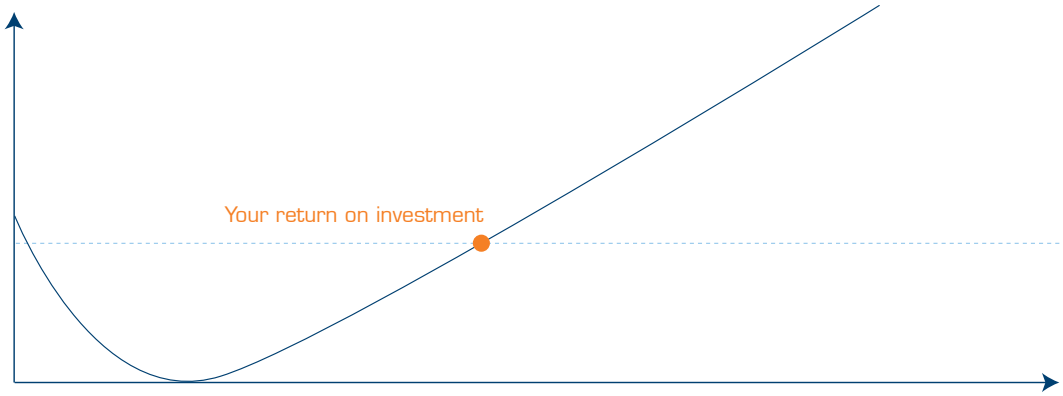
Article

Guidance on how to create a business case for digital pathology



A business case is often required to justify investments in new technology and this is indeed proving true with digital pathology. This paper and the attached calculator aims to help build a business case for organizations to present realistic figures to hospital management and successfully motivate the investment in digital pathology.

This financial business case will provide an ROI (return on investment), but the greatest benefits of digital pathology will extend far beyond the financial savings to the workflow of the pathology department itself. The major gains will be found in quality improvements throughout the entire care process, providing value for several sub-specialties and ultimately, improved patient care. Although benefits such as reduced report turnaround time, increased diagnosis precision and faster treatment decisions are obvious, they are very hard to quantify in a business case.

With that said, presenting a narrower financial model focusing on the increased efficiency and reduced costs for the pathology department itself is easier, and usually provides enough decision data to justify the investment. A financial analysis performed by Williams et al. demonstrates that the investment in digital pathology would be self-funding within the term of the initial contract period (William, Bottoms, Clark & Treanor, 2019).

Steve Holloway (Holloway, 2018) presented a model to describe the digitization level of histopathology containing three levels of adoption (Figure 1). This business case only addresses the highest of the three.

This is because Pantanowitz (Pantanowitz, 2016) argues that, to be disruptive, digital pathology needs to be well integrated from a technical perspective and that processes need to be changed to achieve scalability and efficiency gains. This is also our experience from Level 3 implementations.

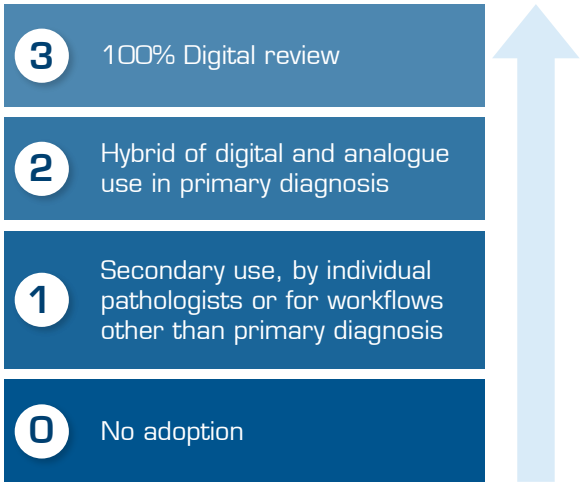


Figure 1. Adapted from Holloway (Holloway, 2018).

SECTRA

Knowledge and passion

This guide focuses on the infrastructure implementation of broad-scale adoption in clinical practice, aiming for 100% digital review. It does not include the benefits of implementing image analysis applications, traditional or AI based. Image analysis has the potential to further improve both patient safety and the business cases.

Since each image analysis application has a specific use case for a particular organ type or disease, each application needs to be evaluated individually. However, having the infrastructure in place is a prerequisite to implement multiple AI applications from different vendors before integrating them into the general workflow.

General implementation tips

This guide refers to digital pathology as 'Whole Slide Imaging implementation' and does not include the digitalization benefits achieved by general digitalization of the lab, such as digital referrals, 2D barcodes on glass slides, specimen tracking at the lab, digital dictation/speech recognition or synoptic reporting. The impact of changes for the lab to implement Level 3 adoption of digital pathology is described in detail by Stathonikos et al. (Stathonikos, Nguyen, Spoto, Verdaasonk & van Diest, 2019) and will not be described in this guide.

A successful implementation depends on the quality of the acquired components, such as the PACS, scanners, networks, and monitors, in combination with a prosperous implementation project with firm change management and a good understanding among staff members of goals and visions. From a technical perspective, it is critical to ensure proper LIS integration, high system reliability, first-rate application performance in the local IT environment, and high image quality.

A guide covering vendor selection has been compiled by KLAS research (KLAS, 2019). Price estimates from digital pathology vendors will be required to prepare cost calculations in the business case.

When business case calculations have been completed, inspiration can be drawn on how to present the business case internally from Williams et al. (Williams et al., 2019). Remember to include demographics such as the growth rate of cases and how to manage changes among staff in order to capture trends and changes.

Non-quantified gains, patient safety and waiting times

Hospital level

In 2014, Ho et al. (Ho, Ahlers, Stratman, Aridor, Pantanowitz, Fine, Kuzmishin, Monalto & Parwani, 2014) calculated at a hospital level that digital pathology can generate savings of $18 million over a five-year period for a US lab with 219,000 annual cases. This corresponds to savings of $85 per case including the savings for increased treatment accuracy. Adjusted for inflation, this corresponds to $93 per case in 2020, giving us an idea of the overall benefit used for a business case.

Hospital-level benefits consist of:

- Increased treatment accuracy leading to overall reduced treatment cost due to greater diagnosis precision
- Shorter turnaround times to meet all contractual SLA's
- Reduced administration and time spent waiting for participants during MDT presentations
- Increased efficiency among other physicians
- A reduction in unnecessary surgeries from accurate diagnoses from the beginning

The pathology department

At the lab level, digital pathology can improve patient safety and reduce lead times. Some examples of quality improvements at the lab that will not be reflected in the business case calculations are listed below:

- Reduced identification errors due to synchronization between LIS system and images. Identification errors have been reported in up to 5% of all cases processed in the pathology laboratory (Nakhleh & Zarbo, 1996) (Nakhleh, Idowu, Souers, Meier & Bekeris, 2011). Digital pathology provides the opportunity of eradicating these errors.
- Instant consultation and peer reviews provide access to sub-specialists to ensure that difficult cases are being reviewed by the appropriate specialist.
- More efficient and higher quality resident training can be performed when given access to a large set of historical cases and direct access to specialists.

Staff benefits

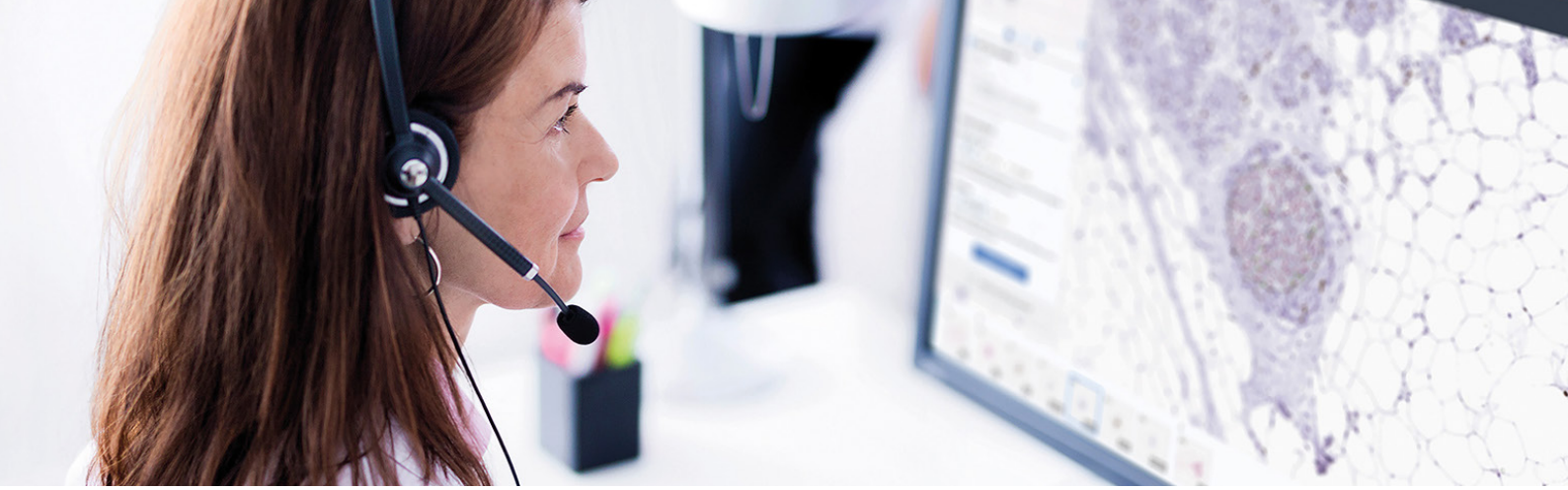
Several users have reported that digital pathology had a positive impact on working conditions. This may lead to a more attractive workplace, a hypothesis that has also been reported in literature.

- Facilitating the recruitment and retention of pathologists (Williams et al., 2019)
- Ability for the pathologist to work from home or a location of their choice
- Improved ergonomics may lead to better well-being for the individual pathologist and reduced sick leave
- Flexible working hours, which is beneficial for the pathologist and their employer

Business case — direct economic impact

Griffin (Griffin & Treanor, 2017) has calculated improvements in productivity of between 10 and 15%, resulting in a break-even at year two, from the introduction of digital pathology. This result can be compared to projected savings of more than $267,000 annually according to calculations carried out at Memorial Sloan Kettering, New York, NY. The savings are mainly derived from personnel restructuring, a decrease in glass slide transportation and ready availability of WSIs, and a reduction in the need for physical storage of glass slides (Hanna, Reuter, Samboy, England, Corsale, Fine, Agaram, Stamelos, Yagi, Hameed, Klimstra & Sirintrapun, 2019). This results in a saving of $3.40 per case, based on an average of 78,000 annual cases. A third estimate from a large lab was calculated to be $12.4 million in savings derived from gains in pathologist time resulting from higher productivity and better workload distribution (Ho et al., 2014). These overall figures take both cost savings and increased income into account.

The three peer reviewed articles present various magnitudes of potential savings and can be used for comparison. By conducting a bottom-up calculation from pathologist efficiency and increased lab efficiency, a more specific figure can be tailored per individual lab.



Individual pathologist efficiency

Real implementation efficiency gains have been reported by Region Skåne (Sandeman & Bauer 2020) with the realization of a reduction in overtime and a decrease in lead times after Level 3 implementation, although the gain in percentage terms has not been calculated. Several studies have measured the percentage increase in pathologist efficiency. The efficiency gains reported vary from 6% (Vodovnik, 2016) up to 13% (Stratman, 2011). The study by Vodovnik measured the reading situation alone while Stratman conducted a theoretical calculation of all work performed by a pathologist. In this business case, we suggest an average of 9.5%.

The efficiency gains come from many different areas. Listed below are efficiencies identified at clinical labs and in the literature.

- **Faster review** due to direct access to cases, image switching, side-by-side viewing, larger field of view with large monitors and access to annotation tools.
- **Internal consultation** can be efficiently performed digitally.
- **More efficient MDT preparation and MDT execution**–without manual glass assembly.
- **Greater competence utilization** can be achieved as workflow balancing can be performed, with only sub-specialized pathologists handling cases relevant to their sub-specialty. For more details, please read article by Azzato et al. (Azzato, Morrissette, Halbiger, Bagg & Daber, 2014).

Savings from increased lab efficiency

The most comprehensive study on lab efficiency identified in the literature reported a 2.63 full-time employee (FTE) equivalent savings for a lab with 220 daily cases in the Netherlands (Baidoshvili et al., 2018). This corresponds to approximately 0.48 FTE per 10,000 annual cases. This reflects another study conducted at Memorial Sloan Kettering, that reported a 3 FTE reduction as a result of eliminating both internal and external glass fetching (Hanna et al., 2019).

Listed below are efficiency improvements identified at clinical labs and in the literature.

- **No need to sort and distribute cases to the right pathologists**. The reduced case assembly for lab technicians was measured at 3 min/case (Baidoshvili, Bucur, van Leeuwen, van der Laak, Kluin & van Diest, 2018).
- **Fewer prior cases need to be retrieved** from the glass archive for comparison. Archival glass slide requests revealed an 93% decrease overall (Hanna et al., 2019).
- **Savings from reduced transportation** have been reported by healthcare organizations with multi-lab or off-site surgical centers. At the off-site surgical centers, pathologists' requests for prior archived material (i.e. glass slides) from patients with anticipated intraoperative consultations revealed a 97% decrease (Hanna et al., 2019).
- **More efficient MDT logistics**, 93 min /MDT meeting (327 min/day for 3.5 daily MDTs) (Baidoshvili et al., 2018).
- **Frozen sections can be distributed more efficiently** to the right pathologist–regardless of their physical reading location.
- **Reduced logistics and administration for external consultation** via digital sharing to labs outside the organization (Leeds (19, 20)), 3 min per request (19 min/day for 6 requests) (Baidoshvili et al., 2018).

- **Reduced logistics when receiving external consultations**, 9 min per request (55 min/day for 6 requests) (Baidoshvili et al., 2018).
- **Faster order processes** for extra stains of 1.3 min per order (47 min/35 cases) (Baidoshvili et al., 2018).
- **Reduction of immunohistochemistry (IHC) test orders**. MSK has reported that following the availability of WSIs in the LIS, IHC orders decreased 30% in cases with documented reviews of prior patient WSIs (Hanna et al., 2019).

Cost reduction

Introducing digital pathology will remove some costs due to improved ways of working and a decrease in the use of outdated technology. Listed below are cost decreases reported.

- Enhanced management capabilities with overview of lead times and outliers will help to **avoid SLA breaches with penalties**. In some organizations, a breach may result in penalties of $1,200 per breach.
- **Removal of transportation costs** between labs for multi-lab organizations.
- **Reduced costs from referring work to commercial laboratory services**: Considerable sums ($46 per case) (Williams et al., 2019).
- Potential **cost reduction for glass archiving** if glasses can be stored off site or disposed of.
- **Savings due to a reduction in microscope investments**. Microscope/camera purchase ($26,500 to $51,600 per annum) (Williams et al., 2019).

Income

The insourcing of cases has a potential to increase income (potentially $46 per case) (Williams et al., 2019).

Investment required

Implementing digital pathology will require new technology. This technology will have an annual cost due to subscriptions and/or depreciation and include annual operational expenditures to maintain and improve the solution. Items with an up-front investment can be calculated as an annual cost based on their service life, i.e. servers and storage. There will also be up-front costs associated with the implementation from the vendor. Note that cost calculations for business cases are not the same as calculations for the capital required to handle cash flow. Both calculations will be required.

The following cost calculation lists the relevant areas to include in an ROI. Contact your Sectra representative for a formal proposal and quotation.

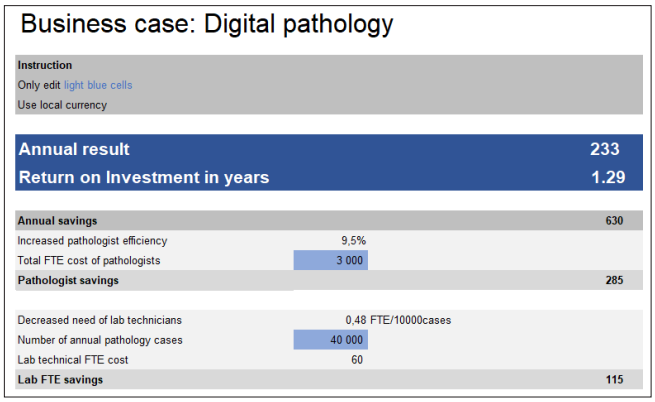
Implementation

Implementing digital pathology comes at an initial cost (not referring to cash flow), both in terms of internal resources within the organization as well as for suppliers of IT and lab equipment.

- Vendor implementation cost
- FTE time for project management, technical implementation, training and validation

Annual cost

- IT infrastructure
  - Servers
  - Hosting, including redundancy
  - Network improvements
- Data storage depending on how long images are stored and the size of the images.
  - Storage time
  - Image size
- PACS
- Scanners
- Clients
  - Computers
  - Monitors
  - Interaction devices
- LIS integrations
- Telepathology services
- Macro cameras



Business case: Digital pathology

Instruction		
Only edit light blue cells		
Use local currency		
Annual result		**233**
Return on Investment in years		**1.29**
Annual savings		**630**
Increased pathologist efficiency	9,5%	
Total FTE cost of pathologists	3 000	
Pathologist savings		**285**
Decreased need of lab technicians	0,48 FTE/10000cases	
Number of annual pathology cases	40 000	
Lab technical FTE cost	60	
Lab FTE savings		**115**

Continue your ROI-calculations in the attached spreadsheet.

Method

For this guide, more than 20 peer-reviewed papers and articles have been examined before combining these findings with Sectra experience from several years of Level 3 implementations of digital pathology.

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