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**Future-proofing Pathology Part 2 – Building a Business Case
 for Digital Pathology**

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9 **Future-proofing Pathology Part 2 – Building a Business Case for Digital Pathology**

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34
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36
37 **Reference count - 17**

Abstract

Diagnostic histopathology departments are experiencing unprecedented economic and service pressures, and many institutions are now considering digital pathology as part of the solution.

In this document, a follow on to our case for adoption report, we provide information and advice to help departments create their own clear, succinct, individualized business case for the clinical deployment of digital pathology.

Introduction

Digital pathology has the potential to revolutionize the way in which pathology services are delivered, and in the current climate, the case for adoption is increasingly compelling. Digital slides are a transformative technology, which will ultimately replace the current standard practice of conventional light microscopy. Whilst the process of whole slide imaging (WSI) adds an additional step to the current laboratory workflow for glass slides, this additional cost is affordable and can be offset by productivity and efficiency gains, direct cost reduction opportunities and cost avoidance opportunities.

In this document, we provide advice on structuring and preparing a salient, succinct business case for digital pathology in your department, based on your own departmental data, and supported by relevant national policy and guidelines. This paper is the follow up to Future-Proofing Pathology : The Case for Clinical Adoption of Digital Pathology¹, and provides complementary information on the financial, commercial and management aspects of digital deployment. A template of business case section headings can be found in Appendix A online.

Structuring the business case

In developing your business case, you should adhere to any local business case templates available in your institution, but the basic outline should include:

- An introduction that describes current pathology processes and digital slide technology in clear, accessible language, suitable for a layperson.
- A compelling description of the need for change within your institution.
- Detail of the scope of investment required, and the principal components of this investment.
- A description of the strategic context of digital pathology, with reference to relevant local, national and international policy and data.
- An economic case, with an options assessment.
- A financial case, including potential cash releasing benefits, cost avoidances
- Non-financial quality and service improvement benefits
- A commercial case
- A management case
- A succinct and convincing conclusion

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3 In the following sections, we will provide outline text, data and references to help you populate these
4 parts of your business case.
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8 **Writing the Introduction**

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10 **The introduction needs to be accessible, and should not presume background knowledge of**
11 **current or future pathology processes. For example**
12

13
14 *In the pathology department, glass slides containing processed and stained human tissue are examined*
15 *using a conventional light microscope to make diagnoses and direct patient treatment pathways.*

16 *Conventional light microscopy has been employed to identify microscopic tissue abnormalities for over a*
17 *century, and this process is the current gold standard technique to provide pathological input into the*
18 *diagnosis and staging of cancers.*
19

20
21 *Digital pathology, or whole slide imaging, is an evolved technology which adds an extra step to the current*
22 *workflow for glass slide production.*
23

24 *In digital pathology, digital images of glass slides are acquired in a scanner using high quality microscope*
25 *lenses. These "whole slide images" are then stored and transmitted, and can be viewed and annotated by*
26 *pathologists on computer display screens. The digital slides are readily available within the department, via*
27 *any networked PC, and have the potential for transmission and sharing within a local, regional, national or*
28 *international network, as well as being made available for remote and out of hours reporting.*
29

30
31 *Whole slide imaging systems have been CE marked for primary diagnostic use in Europe for many years,*
32 *and in spring of 2017, the FDA announced approval for marketing of a whole slide imaging device for*
33 *primary diagnosis in the US². A recent systematic review of the diagnostic accuracy of digital pathology*
34 *versus conventional light microscopy identified 38 quality validation studies of digital pathology, and found*
35 *good rates of concordance between digital and light microscopy diagnosis.³ Various proof of concept*
36 *studies both within and outside of the UK have concluded that digital images are of sufficient quality for*
37 *primary diagnosis of histological specimens.^{4,5}*
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40 **Communicating the need for change**

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42 **In this section, you need to summarize the current pressures on pathology services, at local,**
43 **regional and national level. This can be conveyed in bullet points –**
44

45
46 ***There is wide recognition that there are severe pressures on NHS Pathology services caused by a***
47 ***number of factors creating 'a perfect storm':***
48

- 49
- 50 • *Increasing cancer-associated workloads associated with larger numbers of elderly patients*
51 *often presenting with co-morbidities. Cancer Research UK data shows a 4.5% year on year*
52 *increase in pathology requests.⁶*
53
 - 54 • *Greater complexity of cases with increases in the number of slides per case, the number of*
55 *special stains and markers to be analysed, and the number of data items to be reported as*
56
57
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per the minimum dataset requirements of the Royal College of Pathologist's cancer reporting guidelines.

- A more "time sensitive" culture to ensure cancer patients are diagnosed and treated in a timely manner. The Independent Cancer Taskforce is proposing that by 2020, 50% of patients referred by GPs for cancer checks should have a definitive diagnosis within 2 weeks and 95% within 4 weeks. This is in the face of the evidence that show waiting times are currently lengthening, with the number of patients waiting for more than 6 weeks for a diagnosis increasing by 17% per year since 2010/11.⁷
- Decreasing numbers of clinical pathologists as a result of a prolonged history of insufficient trainee recruitment into pathology with a resultant lack of applicants for vacant histopathology consultant posts.
- A shift in the age demographic of the consultant pathologist workforce. The Royal College of Pathologists figures have shown that 32% of the current Pathologist workforce are >55 years old and are expected to retire within the next 5 years.⁶
- Health systems, including the NHS are under severe economic pressures that prevent funding for workforce expansion and limit investment into new technologies unless they are proven to save money.

Describing the scope of investment

Here, you need to list and describe all the components of the digital pathology system:

- Whole slide imaging scanners - Sited within the laboratory, high throughput automated slide scanners with associated PC workstations scan high volumes of stained microscope slides.
- Workstations with displays - Installed into pathologists offices, they allow the visualization of the slide images at high resolution. Dual monitors are sometimes used to allow simultaneous control of workflow/ case selection/ slide selection and the viewing of the chosen images.
- Information management and technology hardware - The servers (locally or remotely hosted), host the application software described below and may provide short term storage for the images. A webserver can allow image access from any web-browser- enabled PC connected to the institutional network.
- Pathology slide/caseload software - The software manages the clinical caseload and the digital slide images. This includes image creation, workload management, slide viewing, slide sharing, clinical annotation and measurements, report generation and case submission. The software also creates and holds audit trails relating to the activities undertaken for each case. Image analysis software can also be applied to slides to improve the effective quantitation of cell markers (e.g. HER2 in breast cases).
- Interfaces - To the main laboratory information management system (LIMs) or other Electronic Patient Record systems, pulling information relating to patient cases and providing an ability to push any required results/ report information back when the case is complete.

- *Archive database storage solution - The size of any archive storage will depend on the final agreed scope of the investment but the system should retain the images for a sufficient period of time to enable audit and case review. Archive storage architectures would need to be agreed with the supplier as would back-up/ system resilience plans.*

Setting the strategic context

In this section, you need to summarize the international, national, regional and local strategic context for digital pathology, with appropriate references and accurate local data. These are the key points you may want to include:

International

- *World wide access opportunities: One of the key benefits of digital pathology is the easy access it provides to Pathologist expertise. There are numerous areas of the world where access to such expertise is extremely sparse or non-existent. Availability and integration with a digital pathology network would allow substantial clinical benefits for such isolated populations and provide a potential income source for areas where additional pathologist capacity is available or could be created, as has been demonstrated in the US.⁸*
- *Rolling time zone access: In a similar vein, where urgent analysis is required at times when local pathology services are unavailable a 'chase the sun' facility could be put into place where analysis is provided by trusted partners in other time zones across the globe.*

National

- *The National Cancer Taskforce Strategy's paper "Achieving World-Class outcomes; a strategy for England 2015-20"⁷ highlights a drive towards achieving earlier diagnosis, the need to make investment to deliver a modern, high quality cancer service, the need to identify and address workforce capacity gaps, the need to increase diagnostic capacity, and the need to support and streamline regional multidisciplinary team meetings and cancer networks.*
- *Cancer Research UK highlighted the national pressures on Clinical Pathology services in their recent paper Testing times to come? An evaluation of Pathology capacity across the UK (Nov 2016)⁶ identifying the need for institutions to invest into infrastructures to support Digital Pathology and the role that it can play in allowing clinical pathologists to work more flexibly, reducing the impact of workforce shortages, facilitating the operation of clinical networks and reducing subjectivity.*
- *A digital pathology system would meet key elements of the National Information Board's Framework for Action 'Personalised Health and Care 2020'⁹ especially those relating to improved access, personalised medicine, supporting innovation and getting best use from technology. The paper emphasises the importance of links to molecular and genomic medicine (1000 Genome Project). It would also support other information management and technology targets such as moving towards paperless reporting and maximizing the usage of the NHS number.*
- *The National Advisory Group on Health Information Technology's paper Making IT work: harnessing the power of health information technology to improve care in England (August 2016)¹⁰ states clearly that the Advisory Group believes that trying to achieve the aims of the Five Year Forward View without giving highest priority to digitisation would be a costly and painful mistake. The paper acknowledges that while it is natural to seek a short-term financial return on investment (ROI) from health IT, experience has shown that short term ROI is more likely to come in the form of improvements in safety and quality than raw financial terms. Cost savings may take 10 years or more to emerge, since the keys to these gains are reconfiguration of the workforce, local adaptation of digital technologies, and a reimagining of work processes. The paper concludes that*

" to those who wonder whether the NHS can afford the ambitious to digitise in today's environment of austerity and a myriad of ongoing challenges, we believe the answer is clear: the one thing the NHS cannot afford to do is to remain a largely non-digital system".

- The national Chief Clinical Information Officer's (CCIO) 'Newcastle Declaration'¹¹ states that complete, accurate and timely information fundamentally underpins safe and effective health and social care.

Regional sustainability

- The two Carter reviews of pathology^{12,13} both recommended the formation of networked pathology services and the development of "hub and spoke" collaborations. Digital pathology will assist institutions in the flexible use of clinical expertise in relation to laboratory locations, pathologist offices and MDT inputs.
- Include local information on regional collaboration initiatives, sustainability and transformation plans, and how they link with digital pathology

Local context

You can use this paragraph as a template, and collect and insert your own data:

- Workload activity for our organization in 2016 was xxxxxx surgical cases. The projected workload for 2017 is xxxxxx cases. The total number of glass slides reviewed is in the region of xxxxxx per annum. Annual activity growth is in the order of xx% per annum. This increase does not take into account the increasing complexity of the workload, and the extended use of immunohistochemical tests. Taking account of these factors, annual workload growth is in the region of xx % per annum. Over 10 years, surgical specimen caseload has increased by xx %, with xx % increase in consultant establishment. (Figure 2, Figure 3) Comparing 2006 with 2016, consultant productivity levels have increased by xx%. (Table 1).
- There is currently insufficient reporting capacity for workload demand. Additional capacity is delivered at a supplementary rate of x per case / by employing a locum at a salary of xxxxxxxx per annum.
- Of the xx consultant pathologists employed in the department, xx are in the age range of 56-60. In light of staff age demographics, the department will require a robust recruitment strategy to maintain staffing levels over the next few years.
- Include local data on any specialty specific deficits in reporting capacity eg. Gynaepathology, and how networking with other hospitals in the region/allowing for remote reporting by existing staff could prevent reporting backlogs etc.

	Consultant Pathologist Workforce							
	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17
Budget WTE	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Xxx
Contracted WTE	xxx	xxx	xxx	xxx	xxx	xxx	Xxx	xxx

Vacancy WTE	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
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Table 1. Annual departmental consultant workforce vacancies 2009-2017

Creating the economic case / options assessment

This is most easily achieved by considering 2 options: do nothing, or invest in digital pathology.
(see table 2)

Option 1	<p><u>Do Nothing/ Do Minimum</u></p> <p>Continue to use existing microscopy technologies for all cases, transferring tissues and slides to other specialist centres as and when required. Use the continual development of molecular medicine and genetics to further improve services.</p> <p>In this model, consideration will be given to continuing to deliver the service using light microscopy as the sole technology in an environment where the pressures on the service will continue to follow existing and forecast trends.</p>
Option 2	<p><u>Invest in Digital Imaging for Pathology</u></p> <p>Procure/ lease slide scanners, consultant digital workstations, case management and imaging software to undertake the work currently done using Microscopy. The software would be expected to be interfaced to laboratory information systems so that appropriate data can be exchanged safely and securely. A digital image archive is required.</p> <p>In this analysis, a service delivery model will be investigated where certain assumptions are made:</p> <ul style="list-style-type: none"> • all current pathology slides created within the institution will be scanned, stored and made available to consultant pathologists for their analysis • some scanning capability will be available in at least one of the surrounding hospitals • some viewing capability will be available in at least one of the surrounding institutions • viewing capability would be available from hospital employed pathologists' homes • a significant proportion of our pathologists and those located in at least one of the surrounding institutions would be willing to undertake a validation

	<p>process, such that once completed they would then use digital pathology to make primary diagnoses on their caseload</p> <ul style="list-style-type: none"> the pressures on the service will continue to follow existing and forecast trends
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Table 2 – Options regarding investment in digital pathology

In summary when the two options are compared against the key success factors shown below (see table 3), the following scoring is considered valid. (Scores are provided as low=1 (worst), high= 5 (best))

Criteria	Option 1	Option 2
Service Sustainability	2	4
Affordability	3	3
Quality Benefits	1	5
Risks	1	3
Total Scores	7	15

Table 3. Scoring for options 1 and 2.

Financial Case

In the current financial climate being experienced by the NHS it is crucial that wherever possible any new system must be cost-neutral at worst and preferably provide a net position of financial savings for the institution. The costs will vary between institutions based on size, workload, current Consultant workforce relative to establishment, in-house storage capabilities / commercial storage costs and distances between the consultant offices and the laboratory.

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- *Indicative costs show that for a hospital to install the technology as part of a Managed Service Contract the annual costs to the institution are in the region of **£100-200K** dependent on the size of the workload/ consultant pool. This includes costings for the proposed IM&T data storage solution and an interface to the LIMS. The costs would reduce in the event that a region-wide purchase strategy was adopted and further savings may be possible if the purchase of hardware/ peripherals could make use of existing NHS Trust IT suppliers on NHS Framework Agreements and the sharing of data archives. The supplier could also be contracted to provide a hosted data solution if this was preferred.*
 - *Compensating savings – there are significant savings that will mitigate against these costs and could provide a return on investment.*
 - *Funding support – digital pathology fits well with funds being made available nationally/regionally to support the adoption of digital technologies/innovative working/improved diagnosis and early diagnosis.*
 - *Financial cash releasing/generating benefits:
The first 2 cash-releasing savings are predicated on the basis that hospitals across the region would be willing to provide diagnostic support to a neighboring institution due to a shortfall or a lack of specific expertise within its own workforce and that pathologists within the assisting institution have the capacity to undertake the extra work; this would require agreements to negotiated with regard to overtime/ additional sessional payments. Institutions would need to agree a workload 'currency' that takes into account the complexity of work in any exchange/ quid pro quo arrangements. Although such an arrangement could generate hospital to hospital cross-charges (particularly where there is one way traffic) they would not be expected to be of the same order as the current locum / send away costs shown below and would significantly reduce the risks. Any income would also remain within the NHS. In particular, the hospital needing the work done would have far greater levels of confidence and knowledge of the professional ability of the regional pathologist undertaking the work.*
 1. *Reduced locum costs – Locum pathologists are still widely used by many NHS Trusts to cover shortfalls in manpower due to retirement/maternity and carer leave, long term sick leave etc. The overall cost of this is substantial (£140 per hour). Improved productivity and utilization of the existing pathologist workforce using digital pathology, allied with easy transferability of images³³ to trusted colleagues in neighbouring hospitals, should substantially reduce reliance on locum cover.*
 2. *Reduced costs from referring work to commercial laboratory services – Considerable sums (£35 per case) are spent by many NHS Trusts in order to keep abreast of their workloads. The turnaround times of cases outsourced to agencies can be prolonged, given the need for work to be physically transported elsewhere.*
 3. *Potential income generation – Potentially £35 per case. Digital slides create the ability for sites to provide remote clinical diagnosis from images generated anywhere, and will open up insourcing opportunities. Pathologists could undertake work for other institutions within the region, and there is also a market nationally and internationally.*
 4. *Transport savings on Tissue/ Slide Exchange between institutions/sites - (£2-3K per annum). There would be reductions in the logistical costs of relaying slides to reference sites for second/specialist opinions and their subsequent return.*

5. *Microscope/camera purchase - £20K to 40K per annum - Consultant pathologist microscopes currently cost around £25K each. If cameras are also added this can rise to £30K and height adjustable benching to provide the appropriate ergonomic posture for microscopy can add further costs. Although they have a long 'shelf-life' it has been common practice in many hospitals to provide new consultant pathologist staff with a new microscope to ensure the stock of the department is refreshed. Such regular purchases would no longer be necessary*
6. *Reduced archive slide storage/retrieval costs - £2K per annum, £40 per retrieval. Although unlikely to have an impact initially, it is highly likely that costs associated with slide/ tissue storage may be avoided in the future. Where these are off-site and commercially supported these costs are not insignificant*
7. *Reduced financial penalties (£1000 per cancer breach). Avoidance of financial relating to cancer breaches relating to delays in obtaining pathological diagnostic opinion. Insert sample data of the number of breaches in your institution where pathology is likely to have been implicated in delay.*
8. *Reduced litigation costs – Although cases are rare, where institutions have been prosecuted due to diagnostic error relating to pathology, these have proved to be extremely expensive. Post event analysis has shown that such cases could often have been avoided had there been improved quality assurance checking often including a second/ specialist opinion. Apart from the financial aspects, the reputational damage to the institution and the pathology departments can also be severe.*
9. *Earlier diagnosis - £50-100K minimum – Digital imaging can provide quicker turnaround times for cases that require referral to external institutions for regional MDT review*

- Financial, non cash releasing benefits (cost avoidance)-

1. *Time savings for consultant pathologist - There is indicative data suggesting productivity improvements for pathologists when they have adopted digital imaging of between 10-15%.¹⁴ Specific areas where time is saved relate to immediate availability of slides without need to wait for delivery, faster measurements and annotations and easier preparation and compilation of cases for MDT meetings.*
2. *Delayed clinical workforce expansion costs – As cancer workloads continue to grow, hospitals need to expand their pathologist workforce and are experiencing recruitment difficulties. Increased productivity of the existing workforce will help offset these pressures. Applied conservatively this might give an expectation that institutions would be able to absorb additional workload of at least 5%. Consultant annual workload is roughly estimated to be approximately 3,000 cases. A 5% increase in capacity would equate to an extra 150 cases per annum per consultant for the region. Theoretically at least this could increase the number of cases that could be examined by the overall existing pathologist workforce of our region by as much as an additional 12,000 cases per annum. INSERT OWN DATA HERE. xx Consultants performing an additional 150 cases each = xxxx extra cases.
An annual workload increase of 3% = xx Consultants x xxxx cases per annum x 0.03 workload increase = xxxxx more cases each year.
Therefore nearly XXX years of workload increases could be 'absorbed' by the existing workforce, saving approximately £XXX on workforce expansion costs.*

3. *Reduced travel costs - The technology provides consultant pathologists with the ability to work at distance from their laboratories/MDT meeting venues. This could include agile home-working (to cover future 7-day working initiatives) and satellite site working (for MDT attendances). These costs are not substantial in relative terms to the other specified savings.*
4. *Delayed laboratory workforce expansion. Considerable laboratory staff time is undertaken to support current ways of working that could be significantly reduced if digital imaging were adopted. These are as follows:- case assembly, case retrieval, case filing, packing and unpacking dispatched slides, time spent chasing missing/overdue slides, time recutting/restaining lost/damaged slides, time delivering slides to consultants. Assuming a similar 5% efficiency to the consultants for deferment for additional recruitment for x years would create cost-avoidance savings of approximately £XXX per annum.*

Quality Benefits

Digital pathology offers numerous and evolving opportunities to improve patient safety, pathology workflow, service quality and workforce factors, and these benefits are appreciated at multiple levels, by the patient, the pathologist, the institution and the wider network in that institution operates. These benefits have been discussed at length in the part one of Future Proofing Pathology: the case for digital pathology.¹

Direct patient benefits include faster turnaround times for diagnosis, improved access to secondary and expert opinion, and safer, more robust identification of patient specimens and reports. Benefits for the pathologist include safer, more efficient workflows, closer collaboration with colleagues and the opportunity for flexible and remote working. The institution can benefit from leaner workload allocation, paperless reporting, enhanced recruitment and retention, improved training and education, more efficient workflows and faster turnaround times for cancer specimens. The regional network stands to benefit from pooling of reporting expertise and capacity, increased collaboration, workforce flexibility, and faster, safer MDT referral pathways. The innate flexibility of digital reporting also supports opportunities for laboratory consolidation and reorganization of services. In addition to promoting internal sustainability, digital pathology also offers commercial income generating opportunities.

Figure 1, from Future Proofing Pathology Part 1,¹ provides a useful summary of the broad benefits of digital pathology.

Constraints -

In this section, you need to consider the most pressing existing and potential constraints on your plans for digital deployment. These may include the following points:

IT network speeds and capacity - Fast inter-hospital network transfer is necessary.

Physical space in the laboratory – To accommodate scanners.

Physical space in pathologist offices – To accommodate an additional viewing screen.

Digital imaging is not appropriate for all slides – Cytology samples or specific cases requiring polarisation or fluorescence examination are not yet easily accommodated on high throughput scanner. However, such scanners are now becoming available as separate entities if required.

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3 *User Familiarisation - It will take a while for pathologists to become familiar with diagnosis using*
4 *the digital pathology system. The Royal College of Pathologist's 2017 guideline for digital*
5 *pathology recommends an individual validation procedure for each pathologist engaging in*
6 *primary digital diagnosis, and details an approach that provides early exposure to live digital*
7 *reporting, whilst retaining a safety net of glass slide checks, and allowing workflow*
8 *modifications ensure patient safety and professional standards are maintained.*^{15,16}
9 *However, it was also acknowledged that as familiarity in digital pathology grows these*
10 *exceptions would reduce*¹⁷

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13 *Regulatory approval for primary diagnosis with digital imaging- The Royal College of*
14 *Pathologists has published guidelines on the safe adoption and progression of digital*
15 *pathology for clinical diagnosis.*¹⁵ *Recent acceptance of the first Digital Pathology system*
16 *for primary diagnosis by the FDA in the USA should help provide additional confidence levels*
17 *and further momentum.*² *It is anticipated that changes in recommendations relating to the*
18 *retention of slides and tissues will be forthcoming at some future date that these could*
19 *further add to the cost savings of moving to digital pathology.*

20
21 *Scanner throughput - For larger laboratories more than one scanner will be required. Additional*
22 *and failover scanners are included in the business case costs.*

23
24 *Lack of industry standards formats - In the event that there were to be adoption of differing*
25 *commercial solutions across the region this could cause problems as there is as yet no*
26 *industry standard image format approved by regulators. Therefore the use of differing*
27 *systems at differing hospitals could restrict interoperative sharing of images. However, there*
28 *are vendor agnostic middleware suppliers that can provide viewers that will cope with a*
29 *variety of commercially-specific image formats if required although this would probably add*
30 *an extra layer of costs. Suppliers are likely to have to comply with DICOM type standards or*
31 *provide DICOM wrappers in the near future and many already do.*

32
33 *Lack of pump-prime investment funding - The adoption of PACS was nationally funded and led*
34 *to immediate savings from plain film being unnecessary. There is no such underpinning*
35 *national funding for pathology and slide storage would still be required in the short term at*
36 *least while the digital pathology community reviews storage requirements. However, the*
37 *financial analysis within this business case shows that the investment would be self-funding*
38 *within the term of an initial contract period, if savings are met.*

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41 *Existing information management and technology roadmaps and strategies – Any adoption of*
42 *this technology will need to accommodate data storage requirements for short and longer*
43 *term archive access with backup resilience as appropriate. Some strategies can however be*
44 *adopted to reduce overall storage requirements, for example by only retaining selected*
45 *images once reported. This is provided the other cases have glass slides so that repeat digital*
46 *image scanning and analysis can be undertaken should a review of archived cases is needed*
47 *at some point in the future. These capacity requirements must dovetail into existing*
48 *institutional IM&T investment programmes and close liaison with hospital CIOs and their*
49 *forums is essential.*

50
51 *Productivity reductions during 'transition' – While the workforce undertakes the necessary*
52 *training and validation through dual reporting, consultants will be less productive. Leeds*
53 *Teaching Hospitals NHS Trust found an approximate 10% increased workload for*
54 *pathologists undertaking validation.*^(15,16) *The Royal College of Pathologists' new guideline*
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for digital pathology recommends an individual validation for each pathologist that intends to use digital pathology for primary diagnosis, focussed on specimens relevant to their daily work. Dual reporting (primary diagnosis on digital slides, with immediate reconciliation with glass prior to sign out) is recommended for a suitable time period, to ensure adequate exposure and identification of additional training needs, or workflow safety nets.^(15,16)

Ergonomic impact - More time would be spent at computer workstations – where such workstations have not been ergonomically assessed this might add to occupational health issues relating to posture. There are views that the posture for pathologists spending many hours at the microscope is far worse¹⁸ and Pathologists are 'locked' into a viewing position when using a microscope whereas digital pathology allows far greater posture mobility and flexibility. Other environmental factors will need to be assessed and optimised for digital workstation, such as lighting, to ensure that lighting levels are consistent and do not interfere with the ability to read images. Depending on the types of monitors used for primary diagnosis, blackout blinds and controlled artificial light sources may need to be utilised.

The Commercial Case

Your summary of the commercial case for digital pathology may include the following points-

- Spin off technologies further contribute to solutions on offer including computer assisted scoring of marker positive cells (eg HER2), image storage/ archive solutions, image compression, versatile hand-held peripheral devices for Consultants while reviewing images and bioinformatics and 'big data' analysis.
- Higher profile IM &T suppliers to the NHS have already recognised the role that Digital Pathology has to play and have formed commercial partnerships with both scanner, software and biomarker suppliers to offer complete solutions and support services to healthcare providers integrated into other key IM&T systems (eg PAS, LIMS, EPR)
- Such partnerships can also extend to encompass broader imaging access and storage solutions such as Image Exchange Portals and Vendor Neutral Archives where Pathology images could be stored alongside other image types and formats (radiology, medical photography, EEG/ ECG traces etc)
- As a result, for Healthcare Providers who are able to obtain investment funding there is no shortage of suppliers available to respond and an increased likelihood that some of the suppliers will already be providing services to them for other aspects of their existing IM &T services.
- NHS Procurement agencies are all now well aware of the desire of Pathology departments to purchase Digital Imaging capabilities. They have an understanding of the requirement and are inviting suppliers to become part of NHS Framework Agreements which can provide prospective buyers with rapid access to a cohort of 'trusted' IM &T partners who can quickly be taken through a competitive tendering process.
- Procurements in the UK, although initially NHS Trust specific focused, are increasingly Multi-Trust level as institutions form collaboratives as part of Sustainability and Transformation Plans (STP).
- As Pathology services have increasingly turned to Managed Service Contracts for their equipment provision it is highly likely that this 'new' technology will be embraced in a similar way to create

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3 *more effective use of finance and link into solution refreshment as contractual periods approach*
4 *their endpoints.*
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6 **The Management Case**

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8 Your management case may include the following:

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10 - *Once procurement is complete the implementation timescales and resource required will very much*
11 *depend on the scope of the investment (ie single Trust/ Multi-Trust) and the number and scale of IT*
12 *systems that require interfacing.*
13
14 - *The installation of the scanner(s) into the laboratories and the workstations into the Consultants*
15 *offices and MDT rooms is fairly straightforward provided there is the necessary space and utilities*
16 *provision (power, UPS, network points).*
17
18 - *The interconnectivity of multisite deployments will require significant liaison between hospital*
19 *network managers and Information Governance/ Caldicott Guardian leads. These staff are vital to*
20 *ensure that images and image information relayed between organisations are both secure and*
21 *appropriate. The connectivity itself should not be difficult to achieve but engaging the right*
22 *hospital representatives to understand the requirement and agree the correct processes can be*
23 *time consuming.*
24
25 - *Interface development, testing and go-live are often the most time-consuming and error-prone*
26 *elements of an implementation and therefore planning/ testing should commence early with the*
27 *parties concerned.*
28
29 - *The implementation of digital WSI scanning and its use for MDT review, primary diagnosis and*
30 *reporting has significant implications for workflow and resource utilisation through the whole of*
31 *the Pathology pathway and therefore it is crucial that the working processes are subjected to*
32 *LEAN/six-sigma type analysis in the earliest stages of the implementation. This should help to*
33 *ensure that departments make best use of the technology and maximise benefits realisation by*
34 *cutting out 'wasted' resource and ensuring that savings are delivered in terms of both time and*
35 *finance.*
36
37 - *The technology may be disruptive during its implementation. Some Consultant pathologists are*
38 *keen to adopt digital pathology as part of their day-to-day working and willing to undergo the*
39 *necessary validation processes that will be required as part of the transformation of their working.*
40 *Others however will be less certain and may be less adept at or willing to move to such a*
41 *technology. It is clear too that digital image review is not currently seen to be appropriate for all*
42 *types of tissues/ cancers and therefore it is inevitable that adoption of the new technology will*
43 *need to be undertaken in a carefully planned and staged / phased process with clear timelines and*
44 *targets.*
45
46 - *It is crucial that the requirement for clinical validation (and the dual reporting overhead that this*
47 *requires) are included in the resource planning for the implementation.*
48
49 - *For full adoption it is most likely that implementation will be phased over a two to three year period*
50 *and at the end of that time there would still be the requirement for microscopy for some tissues*
51 *and specialisms (ie a mixed economy is forecast for the foreseeable future as technology stands,*
52 *based on the broad range of tissues and cancers currently reviewed in most institutions.*
53

54 **Conclusion**

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Digital pathology can provide considerable economic and quality benefits to the examination of tissues for Pathology purposes. While the technology is not yet able to accommodate all facets of the diagnostic reporting, considerable strides have been made and the technology is now ready for adoption into mainstream pathology. The technology will continue to progress and as it develops further this will only broaden the scope of its benefits.

It is believed that in financial terms the system can be cost effective through improvements in productivity of the service as a whole and in the impact it can have on both care pathways and therapeutics.

When this is married to quality benefits, the creation of flexible working capabilities for pathologists, risk reductions and the support it can provide for service sustainability the business case is robust. Furthermore the adoption of a system that allows facilitated sharing of pathology images can be an enabler for pathology collaborations and consolidations where these are required.

We hope you have found this discussion, and the illustrations of how to populate the sections of your business case for digital pathology helpful and informative, and would encourage the reader to utilize parts of this document in their own business case submissions.

REFERENCES

1. Williams BJ, Bottoms D, Treanor DE. Future-Proofing Pathology: the case for clinical adoption of digital pathology.
2. Food and Drug Administration, USA. FDA allows marketing of first whole slide imaging system for digital pathology. 12th April 2017. News release available from <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm552742.html> last accessed 31/05/2017
3. Goacher E, Randell R, Williams B, Treanor D. The diagnostic concordance of whole slide imaging and light microscopy. A systematic review. Arch Pathol Lab Med. Vol 141. January 2017.
4. Snead D, Tsang Y-W, Meskiri A, Kimani P, Crossman R, Rajpoot N et al. Validation of digital pathology imaging for primary histopathological diagnosis. Histopathology. 2015; 68:7;1063-72.
5. Bauer TW, Schoenfield L, Slaw RJ, Yerian L, Sun Z, Henricks WH. Validation of whole slide imaging for primary diagnosis in surgical pathology. Arch. Pathol. Lab. Med. 2013; 137; 518-524.
6. Cancer Research UK, (2016) Testing times to come? An evaluation of pathology capacity across the UK. Available from: http://www.cancerresearchuk.org/sites/default/files/testing_times_to_come_nov_16_cruc.pdf Last accessed: Feb 10th 2017.
7. Report of the Independent Cancer Taskforce, UK, (July 2015) Achieving World Class Cancer Outcomes: A Strategy for England 2015-2020. Available from: http://www.cancerresearchuk.org/sites/default/files/achieving_worldclass_cancer_outcomes_a_strategy_for_england_2015-2020.pdf Last accessed: Feb 10th 2017.
8. Zhao C, Wu T, Ding X, Parwani AV, Chen H, McHugh J, et al. International telepathology consultation: Three years of experience between the University of Pittsburgh Medical Center and KingMed Diagnostics in China. J Pathol Inform 2015;6:63. Available from <http://www.jpathinformatics.org/text.asp?2015/6/1/63/170650> Last accessed: Feb 10th 2017.
9. National Information Board, UK, Personalised Health and Care 2020. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf Last accessed: Feb 10th 2017.
10. National Advisory Group on Health Information Technology, UK, (Aug 2016) Making IT work: harnessing the power of health information to improve care in England. Available from

1
2
3 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/Wachter_Review_Accessible.pdf Last
4 accessed: Feb 10th 2017.

5
6 11. CCIO Network, UK. The Newcastle Declaration. Available from:
7 http://www.digitalhealth.net/includes/images/news0254/PDF/Newcastle_Declaration_interactive_doc.pdf. Last accessed 30th
8 May 2017.

9
10 12. Lord Carter of Coles, Report of the review of NHS pathology services in England. 2006.
11 <http://webarchive.nationalarchives.gov.uk/20130107105354> (accessed 10 Feb 2017).

12
13 13. Lord Carter of Coles, Review of operational productivity in NHS Providers. 2015.
14 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/434202/carter-interim-report.pdf (accessed 10
15 Feb 2017).

16
17 14. Stratman C, Drogowski L, Ho J. *Digital Pathology in the Clinical Workflow: A Time & Motion Study* [conference presentation].
18 Pathology Visions; October 24-27; San Diego, CA; 2010. Available from: <https://digitalpathologyassociation.org/pathology-visions-2010>. Last accessed: Feb 10th 2017.

19
20 15. Royal College of Pathologists, UK. Guideline for Digital Pathology. 2017.

21
22 16. Williams BJ, Hanby A, Millican-Slater R, Nijhawan A, Verghese E, Treanor D. Digital Pathology for the Primary Diagnosis of
23 Breast Histopathological Specimens: An Innovative Validation and Concordance Study. *Histopathology*. Accepted for
24 publication September 2017. Available as an advance online at <http://onlinelibrary.wiley.com/doi/10.1111/his.13403/abstract>

25
26 17. Randell R et al. Virtual reality microscope versus conventional microscope regarding time to diagnosis: an experimental
27 study. *Histopathology* 2013;62:351-8

28
29 18. George E. Microscope use and musculoskeletal disorders. *Am J Clin Pathol* 2010;133:543-548

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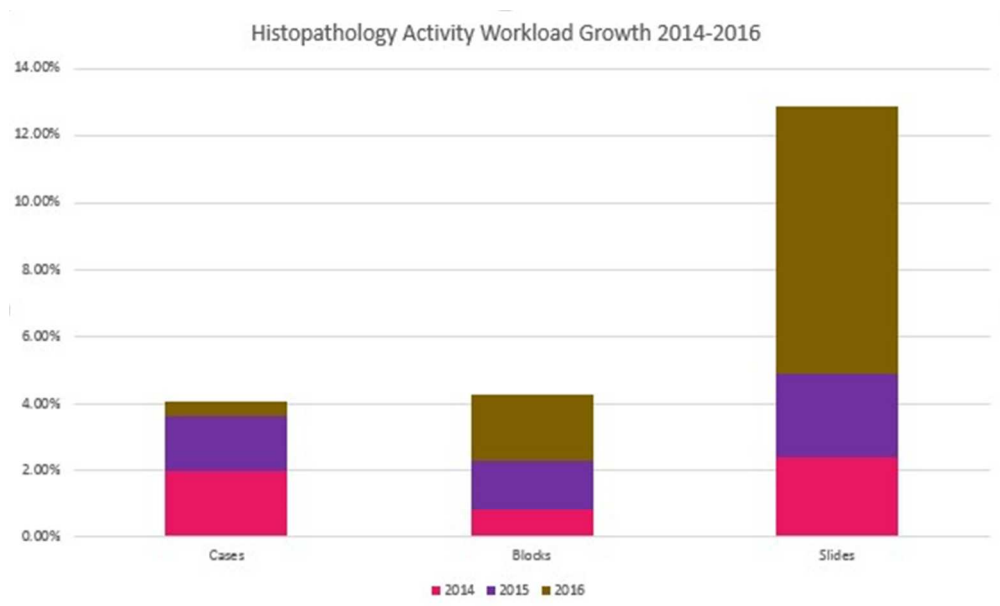


Figure 1. Illustrative departmental workload statistics

153x92mm (96 x 96 DPI)

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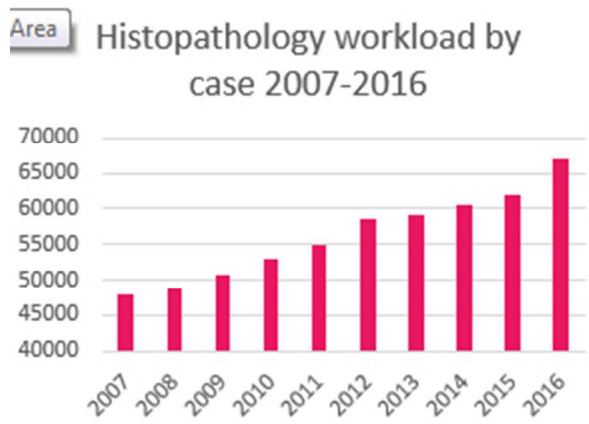


Figure 2. Illustrative departmental workload statistics : workload by case

79x57mm (96 x 96 DPI)

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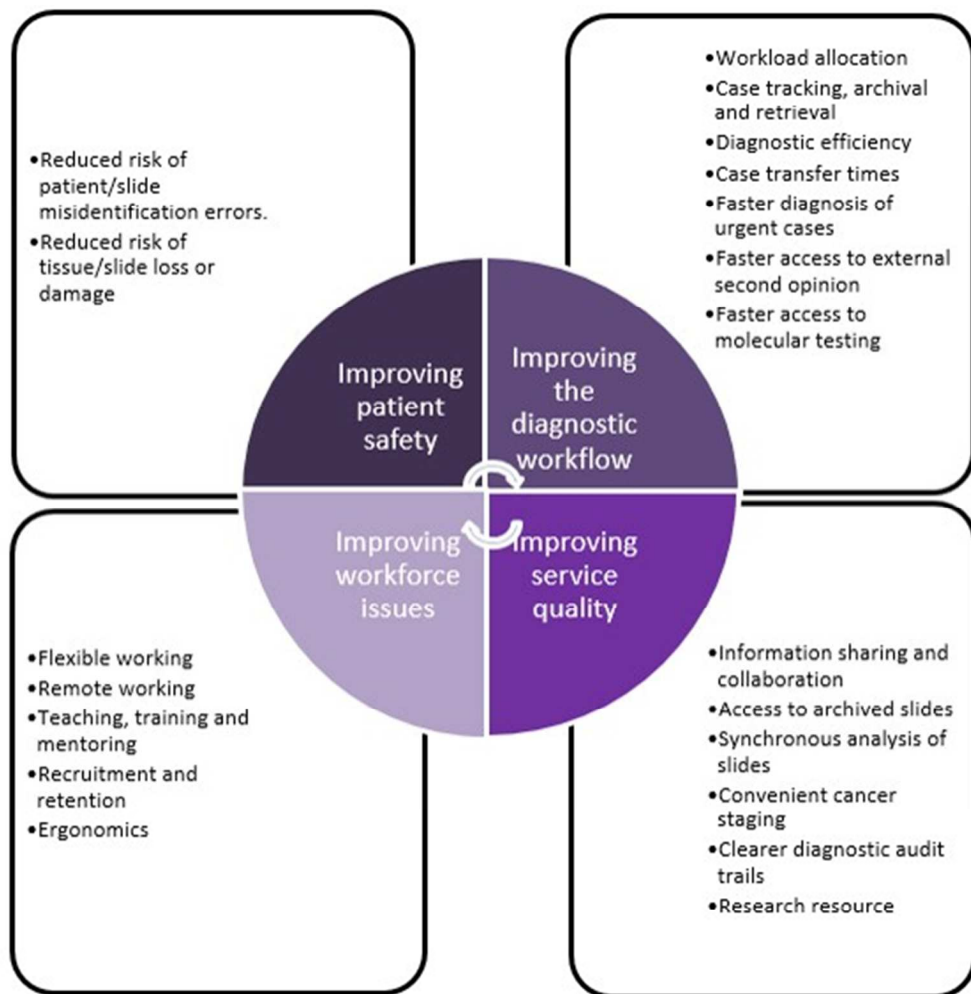


Figure 3. The benefits of digital pathology.

120x120mm (120 x 120 DPI)

Appendix A.**Template Headings for a Business Case for Digital Pathology****1. Introduction****2. The need for change****3. Scope of required investment****4. The strategic context**

- international

- national

- regional

- local

5. The economic case

- to include options assessment (do nothing versus invest in digital pathology)

6. The financial case

- financial cash releasing/generating benefits

- financial non-cash releasing benefits (cost avoidance)

- quality benefits

7. Constraints**8. The commercial case****9. The management case****10. Conclusion**