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ORIGINAL ARTICLE

Practical considerations for pathologists when selecting digital pathology systems: an ESDIP guide

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Abstract

The implementation of digital pathology (DP) has been reported across academic, public, and private laboratory settings, providing valuable insights into workflow transformation. However, comparatively little guidance exists on how DP systems should be evaluated prior to acquisition and deployment. Given the substantial financial investment and long-term strategic implications of DP infrastructure, a structured and context-aware evaluation process is essential. In this practical guide, developed by the European Society of Digital and Integrative Pathology (ESDIP) https://www.esdipath.org/, we outline a comprehensive approach for the pre-deployment assessment of DP systems. Drawing on collective experience from multiple institutions and supported by relevant literature, we describe key parameters to consider when evaluating the core components of the DP ecosystem: whole slide scanners, image management systems, workstations, storage infrastructure, and laboratory information systems. We highlight methodological differences between large-scale multisite procurement processes and single-institution implementations, emphasising realistic workload testing, interoperability, and long-term scalability. By integrating technical and clinical perspectives, this guide aims to support pathology departments, IT teams, and institutional decision-makers in selecting DP solutions aligned with their specific institutional needs, infrastructure capabilities, and the future integration of computational pathology.
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Introduction

Digital pathology (DP) implementation has now been described across multiple institutional contexts [1,2], including multisite deployments [3–8], single public pathology departments [9–11], and private laboratory environments [12–14]. These reports provide valuable operational insights and have contributed to consolidating DP deployment in recent years [15]. However, while deployment strategies and post-implementation experiences are relatively well documented, the literature offers comparatively limited guidance on how DP systems should be evaluated before acquisition, particularly during the tender and pre-deployment phases [6,16,17].

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This gap is non-trivial. The procurement of DP infrastructure represents a high-cost, long-term strategic investment with direct implications for diagnostic efficiency and future readiness for computational pathology (CPath) and artificial intelligence (AI)-supported workflows.

Furthermore, evaluation requirements can differ substantially across settings: large public tenders and multisite network demand differ from single-institution implementations. Whereas the former generally require structured tender documentation and extensive comparative testing across vendors, the latter often operate under practical constraints that limit the feasibility of prolonged on-site evaluations, thereby requiring more targeted, resource-efficient assessment approaches.

Irrespective of deployment scale, an effective evaluation process should begin with a clear definition of the intended scope and functional requirements, including expected slide volume, long-term archiving strategy, and integration needs with the laboratory information system (LIS). Equally important is the definition of the available budget and financial constraints, not only for initial deployment but for long-term sustainability, as DP solutions entail substantial cost components beyond acquisition, namely software updates, user licensing, storage maintenance, and infrastructure scaling. Establishing these parameters up front is essential to ensuring alignment between procurement decisions and the laboratory's clinical objectives, while minimizing the risk of selecting solutions that cannot sustain the intended digital workflow.

While comprehensive quantitative data on DP implementation rates at European and global level are still limited, available evidence from the European Society of Digital and Integrative Pathology (ESDIP) digital map initiative (https://www.esdipath.org/map-of-digital-pathology-labs/) indicates a heterogeneous and evolving landscape of adoption across European institutions.

In this context, this practical guide from the ESDIP provides a structured overview of how to set up an evaluation for DP systems, with particular attention devoted to the methodological differences between multisite procurement scenarios and single-site implementations.

Materials and methods

This work was developed by the ESDIP – a multidisciplinary European scientific organisation, joining pathologists, researchers, and other professionals, dedicated to advancing digital and integrative pathology through research and education – as a practical guide describing how to structure and execute a pre-acquisition evaluation of DP systems. It is a practice-based, observational analysis derived from the routine deployment and longitudinal use of DP hardware and software systems. Evaluation parameters were identified through an iterative process among co-authors, deriving from cumulative hands-on experience with DP systems across routine clinical workflows in different settings, ranging from public health departments to private practice laboratories and encompassing both single-institution deployments (e.g. Institute of Tissue Medicine and Pathology of the University of Bern in Switzerland, IMP Diagnostics in Portugal [12], Institute of Pathology at Helios Kliniken Berlin and the Institute of Pathology of the University Hospital Aachen in Germany) and multisite implementations (e.g. DigiPatICS project led by the Catalan Health Institute [5] and the deployment in the Lombardy region in Italy [18]). Specific brand names for DP hardware and software were intentionally not included to avoid potential conflicts of interest and to ensure this framework remains applicable over time despite the continuous evolution of commercial solutions.

In addition to practice-based experience, relevant literature was consulted to contextualise the proposed evaluation framework. Articles were selected based on relevance to DP implementation, scanner and image management systems (IMS) evaluation, LIS integration, storage and infrastructure planning, and procurement/tender experiences. References were identified through author knowledge, citation tracking, and targeted search in PubMed (https://pubmed.ncbi.nlm.nih.gov/). The selected publications were used to support key criteria commonly applied across institutions. The study is organised in different sections detailing key parameters when evaluating DP scanners, IMS, workstations, LIS integration, and storage infrastructures, aiming to support decision-making in DP acquisition (Figure 1). Structured evaluation checklists on how to evaluate the different components of DP deployment are also provided in the supplementary material, Tables S1–S5.

We acknowledge that certain concepts overlap across the following sections, which is expected as it reflects the intrinsic interdependence between hardware, software, storage, and workflow components within an integrated DP ecosystem. Further, this deliberate reiteration ensures that readers can obtain a comprehensive understanding of each topic, even when consulting a specific section in isolation.

Results

Setting up an evaluation of DP systems

While the DP deployment across different settings is well documented [1,4–6,9,11–14], the literature provides comparatively limited detail on how systems are evaluated during the tender and pre-deployment phases [6,17]. This gap is particularly relevant given that evaluation requirements vary substantially with the deployment context, with multisite and public tender scenarios differing fundamentally from single-laboratory implementations.

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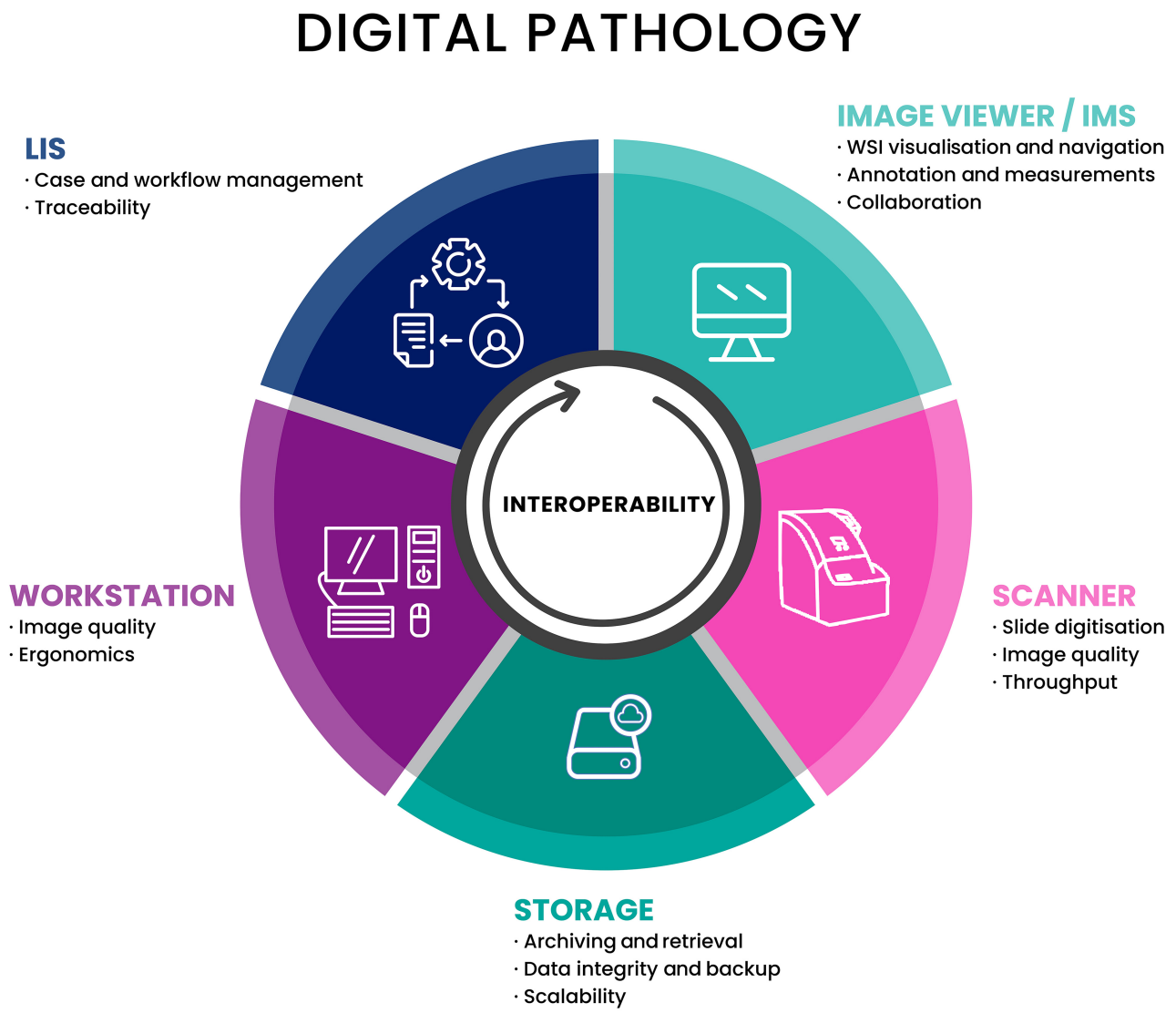


Figure 1. Core components of a typical DP system. Interoperability is a transversal requirement across all elements.

Irrespective of the context, the evaluation process should begin with a clear definition of the system's intended scope and functional requirements. This includes determining whether whole slide images (WSIs) will be archived long-term, the degree of integration required with the existing LIS, the modalities to be incorporated [such as direct immunofluorescence, fluorescence *in situ* hybridisation (FISH), or macroscopic imaging], and the expected slide volume. Also important is to consider whether the DP system will also be used for research, which may impose different requirements. Establishing these parameters early ensures that the evaluation criteria are aligned with the laboratory's strategic objectives and prevents the acquisition of systems that cannot support the desired digital workflow.

Large-scale implementation in multisite and public healthcare settings

Regarding public, multisite implementations, once the scope is defined, the evaluation should adopt a formalised scoring framework that combines objective, standardised criteria with expert judgement. The DigiPatICS project [5] followed this dual-layer approach by employing a 100-point matrix that balanced measurable technical specifications with qualitative assessments from pathologists and IT specialists (provided in the supplementary material, File S1). Objective criteria encompassed economic considerations, vendor certifications, storage architecture, and the capabilities of the image management platform. In parallel, domain experts assessed scanner performance, diagnostic viewer usability, integration architecture, training provisions, and the system's capacity to support advanced functionalities such as AI. This hybrid model ensured that both technical rigour and clinical relevance were captured in the final evaluation. A critical component of the assessment involved structured technical testing performed under conditions that closely replicated routine clinical activity. This phase was intentionally designed to move beyond theoretical specifications and vendor-provided benchmarks, which can be extremely difficult to compare, by subjecting each system to large-scale,

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high-intensity stress tests. Over the course of a full week, scanners were required to process thousands of consecutive routine slides originating from multiple hospitals, encompassing the full variability of real specimens, including suboptimal preparations (e.g. thick sections, slides with minor coverslip imperfections), using a sample as close to reality as possible. This approach enabled evaluators to assess effective throughput, taking into account slide-handling failures, rescans, jamming events, and the impact of continuous operation on image quality stability. Such testing revealed performance characteristics that are not apparent in controlled demonstrations, including how scanners behaved when operating at maximum capacity for extended periods.

In parallel, the evaluation included a detailed assessment of the diagnostic viewer, and pathologists from different subspecialties assessed the smoothness of navigation and the system's ability to load and stream large images without latency. Particular attention was paid to the usability of annotation and measurement tools, the synchronisation of multiple slides within a case, and the handling of advanced imaging modalities such as fluorescence, Z-stacks, and multilayered images. These tests ensured that the viewer could support not only routine histopathology but also more demanding diagnostic scenarios. In the DigiPatICS project, the IMS was a distinct component from the diagnostic viewer and underwent an equally comprehensive evaluation. Beyond basic storage and retrieval, it was tested for its capacity to manage complex case structures, integrate metadata from the LIS, and maintain traceability across the entire diagnostic workflow. Evaluators examined how efficiently the platform handled high-volume data ingestion, whether it supported telepathology and remote consultation, and how seamlessly it integrated with existing hospital information systems (HISs). The platform's ability to support teaching modules, research repositories, and future AI-driven applications was also scrutinised, reflecting the long-term strategic role of DP infrastructure. Together, these empirical tests provided a holistic and evidence-based understanding of system performance, capturing not only technical specifications but also operational behaviour under realistic workload conditions. It is important to mention that this level of in-depth, large-scale pre-deployment testing is generally limited to major multisite or public tenders, while smaller, single-site implementations have practical and commercial constraints. Usually, only network-level initiatives are able to undertake such evaluations, as they possess the necessary organisational capacity to perform such extensive testing. More critically, from the vendors' perspective, participation in prolonged, resource-intensive evaluation processes is typically only feasible when the scope and potential impact of the deployment justify the substantial investment required.

Single site and private healthcare settings

For single-institution sites, while the same parameters described previously remain relevant, the evaluation strategy must be adapted. Due to the impracticality of gathering multiple vendors for a prolonged on-site test, single-institution assessments must focus on the most feasible vendors, using available information, conference open demonstrations, and preliminary discussions to preselect candidates and then conduct targeted testing. Some vendors will provide the opportunity to test equipment on site (i.e. scanners), while others will only propose pilot scanning of representative case sets (off-site). In the more constrained setting of single institutions, also consider visiting external sites where the systems under consideration are already deployed and to gather feedback from actual users, in order to gain practical insights into real-world usability that cannot be fully captured through vendor demonstrations or pilot testing. Vendors may facilitate this process by providing institutional references to be contacted. Moreover, establishing an objective evaluation grid (for hardware and software options), compiling all the relevant parameters for the institution and integrating the appraisal of pathologists, lab managers, and IT specialists is essential. This will allow for a thorough comparison of candidate systems and support final decision-making. The following sections provide information to support a comprehensive evaluation process, consolidate key assessment parameters, and are designed to support both large multisite deployments and smaller single-site implementations. Corresponding structured checklists for each component are provided in the supplementary material, Tables S1–S5 to facilitate practical application of these criteria.

Parameters to evaluate when acquiring DP scanners

Whole-slide scanners represent the foundational hardware component of DP systems, directly determining image acquisition quality and workflow efficiency. Scanner procurement, as for other DP components, should involve pathology departments, IT teams, and operational leadership to ensure technical compatibility and sustainable deployment. The following parameters provide a structured framework for evaluating scanners, whether for institutions already committed to DP or those evaluating initial deployment.

Usability parameters

Throughput and operational capacity

Realistic assessment of scanner throughput is essential for matching capacity to institutional needs [19,20]. Scanner architectures range from compact bench-top units holding 1–20 slides to high-throughput systems with total capacities of 300–1,000+ slides. Within larger scanners, slides are organised in racks (typically 20–30 slides each), enabling modular loading and unloading. While vendors specify maximum speeds, real-world performance depends on tissue complexity, slide quality, and operational interruptions. Continuous loading enables uninterrupted operation as magazines are swapped. The ability to prioritise urgent slides without halting batch processing accommodates stat cases.

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For scanners supporting whole-mount slides, the number and placement of dedicated rack slots should be evaluated, as limited capacity can constrain throughput when large-format slides are scanned alongside routine cases. For multisite networks, standardisation using identical scanner models simplifies training and enables interchangeable maintenance. Redundancy planning prevents single points of failure, ensuring an uninterrupted diagnostic workflow. Remote monitoring enables centralised oversight of scanner fleet status across multiple locations. Whenever feasible, practical evaluation should include testing with representative workloads and peak volume scenarios.

Slide handling and compatibility

Scanner compatibility with institutional slide types is operationally critical. Standard slides (25 × 75 mm) are universally supported, but oversized slide compatibility varies. Coverslip tolerance – glass or film, thickness variations – affects focus reliability and should be verified with institutional protocols. Integrated barcode readers must reliably capture specimen identifiers, including externally generated labels, particularly for referral cases, biobanks, and multicentre studies. Jam handling capabilities minimise workflow disruptions. For institutions performing cytology, compatibility with cytology slides and cell blocks should be verified, although dedicated systems may be required to ensure optimal image quality in this setting. Testing with representative institutional slide samples is recommended, if feasible. Further, checking for rack compatibility with existing automated stainers is equally important, as it can improve workflow efficiency.

Ergonomics and user experience

Physical footprint, environmental requirements, and noise levels must fit laboratory infrastructure. Scanner software interfaces should provide intuitive controls for scan initiation, preview, and queue management. Remote operation capabilities improve flexibility for high-throughput or after-hours scanning. Maintenance accessibility for routine cleaning and consumable replacement should be straightforward.

Infrastructure-related parameters

Integration and interoperability

Seamless integration with LIS, storage infrastructure, and IMS is essential [21,22]. Bidirectional LIS integration enables automated worklist retrieval and metadata exchange. Digital Imaging and Communications in Medicine (DICOM) Supplement 145 compliance facilitates standards-based interoperability, reducing vendor lock-in. Network connectivity should be 1 Gigabit Ethernet minimum, with 10 Gigabit preferred, and must align with existing infrastructure. For multisite networks, centralised versus federated architectures present different trade-offs. Unified worklist management and cross-site WSI accessibility are critical where pathologists interpret cases scanned at other sites. Standardised protocols across network sites ensure consistency. Remote diagnostics enable vendor troubleshooting across distributed fleets. Automated quality control features support ongoing performance monitoring. Practical evaluation should verify LIS compatibility and test network bandwidth for multisite transfers.

Image acquisition parameters

Image quality and optical specifications

Image quality fundamentally determines diagnostic applicability [19,21]. Standard resolutions of 0.24–0.26 µm/pixel (40× equivalent) suffice for routine histopathology, while 0.18–0.20 µm/pixel may be required for cytology or specialised applications. Colour fidelity is critical; scanners should provide calibration capabilities and consistent illumination. LED-based illumination offers advantages including longer lifespan and improved colour stability over halogen sources. Image artefacts (stitching errors, out-of-focus regions, uneven illumination) should be minimised. Native DICOM support facilitates standards-based interoperability, though many scanners still use proprietary formats with optional conversion [22].

Focus and tissue detection

Autofocus performance determines image sharpness and reliability [20]. Multipoint or continuous autofocus systems better accommodate tissue thickness variations and coverslip irregularities than single-point systems. Z-stacking capabilities (scanning multiple focal planes with configurable spacing) can be necessary for thick sections and cytology, though they increase scanning time and storage requirements. Extended depth-of-field algorithms fuse multiple focal planes into a single, uniformly sharp image. Tissue detection algorithms must accurately distinguish tissue from background, reducing scan times and storage consumption. Testing should include slides with thick sections, wrinkled coverslips, and air bubbles to evaluate autofocus robustness. It should also assess the accurate detection and capture of the on-slide controls. Practical evaluation could also test challenging specimens such as adipose tissue and bone, comparing scanner output to conventional microscopy for colour accuracy and diagnostic equivalence.

Advanced imaging capabilities

While brightfield scanning remains most common for routine diagnostics, advanced capabilities are increasingly important for molecular diagnostics and AI applications [23,24]. Fluorescence imaging requires filter sets matching institutional assays (DAPI, FITC, TRITC, Cy5). LED excitation sources offer superior longevity over mercury/xenon lamps. Sensitivity and dynamic range, determined by bit depth (12- and 16-bit) and signal-to-noise ratio, are critical for FISH or immunofluorescence [25]. Multichannel acquisition must provide

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accurate channel registration. Multispectral imaging with spectral unmixing supports multiplexed immunofluorescence assays [24,26]. Z-stacking with configurable depth range (10–100 μm) enables three-dimensional (3D) reconstruction and extended depth-of-field generation. Specialised modalities, such as brightfield-fluorescence co-registration, polarised light, or phase contrast, may be required for specific applications. For molecular pathology laboratories, these capabilities are essential; for general surgical pathology, they can represent future-proofing investments. Testing should include representative FISH slides to verify signal detection and background suppression.

Other factors

Regulatory compliance and support

Regulatory requirements vary by region and intended use [19,27]. European Union scanners for diagnostic use require In Vitro Diagnostic Medical Device Regulation (IVDR) compliance and Conformité Européenne (CE) marking. United States diagnostic applications require Food and Drug Administration (FDA) 510 (k) clearance. Other frameworks include Health Canada, the Pharmaceuticals and Medical Devices Agency (Japan), and the Therapeutic Goods Administration (Australia). Institutions must verify scanner regulatory status aligns with the intended use. Vendor support for clinical validation facilitates regulatory submissions. Training programmes should provide comprehensive education for operators and IT staff. Technical support response times and service contract terms should be clearly defined. As stated by Clarke *et al* [6], 'vendor accountability and performance expectations can be achieved through well-defined contracts', highlighting the importance of explicit service-level agreements and clearly delineated performance obligations to safeguard operational continuity. Lastly, for global organisations, verify vendor support infrastructure in relevant countries.

Cost and operational considerations

Scanner acquisition requires a comprehensive financial analysis beyond the purchase price. Total cost of ownership (TCO) incorporates maintenance contracts, consumables, energy consumption, and IT support. Cost-per-slide calculations should account for utilisation rates, lifespan, and downtime. As a general benchmark, cost-per-slide estimates from national-level analyses in European public healthcare systems (namely the French Policy for the digitalisation of anatomic and cytopathology) suggest values of approximately €2.8 per slide, although this may vary. Scalability costs, including those adding capacity or capabilities, should be evaluated for anticipated growth. Technology replacement cycles, typically 5–10 years, should be factored into planning. Multisite networks benefit from volume purchasing but must plan coordinated upgrade cycles. Beyond direct costs, potential cost offsets enabled by DP, such as reduced physical slide transport, support for remote consultations and second opinions, more efficient use of subspecialty expertise across sites, and decreased reliance on duplicate slide preparation, may further influence overall cost–benefit considerations, depending on institutional workflows. A corresponding evaluation checklist for DP software is available in the supplementary material, Tables S1–S5.

Parameters to evaluate when acquiring DP software

While the DP IMS can extend beyond image visualisation to include storage, metadata, and workflow infrastructure, and the 'viewer' strictly represents only the front-end visualisation component of the IMS, in routine, non-technical contexts, the two terms are often used interchangeably. In this practical sense, the IMS is often referred to as the 'viewer' or 'viewing system' and represents the primary interface between the pathologist and WSIs, making its performance and usability critical determinants of diagnostic efficiency and user acceptance. Importantly, some of the functionalities referred to in this section could alternatively be available in the integrated LIS, instead of the IMS/viewing system (e.g. some LIS may display the slide tray and case details, and this is not presented by the IMS). Likewise, the image viewer may exist as a standalone component separate from the IMS [5]. In the end, the overall solution, encompassing both IMS/viewer and LIS components, should support a coherent diagnostic workflow, regardless of how specific functionalities are distributed across systems.

Usability parameters

Software performance

The software performance should be assessed under realistic conditions whenever possible, as suboptimal performance will negatively impact turnaround time and user experience. This encompasses the appraisal of image loading time and responsiveness during navigation. For larger institutions or multi-user environments, benchmarking multiple vendors, with concurrent users and representative slide batches, can provide meaningful insights into performance. For single institutions or smaller practices, performance assessment is often more limited as there may be insufficient resources and vendors may have limited incentive to support extensive benchmarking. In this context, beyond relying on vendor-provided demonstrations, which are typically one-off events, we recommend that, for the platforms identified as most promising after an initial screening, institutions request time-limited access to a demo environment (sufficient to allow users to assess suitability for their specific needs). Nonetheless, users should be aware that demo environments will not fully replicate real-world functioning. Consulting with existing users and, where possible, observing or testing their systems on site can also provide valuable practical insights into real-world system performance.

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Software panel and navigation

Assess whether the software's layout and menu structure support intuitive workflow (e.g. Are the slide's labels and case identification readily visible? Is the virtual tray optimised for your workflow?). Evaluate whether frequently used functions are easily accessible and whether navigation between slides and cases is smooth, as well as the navigation within the slide (e.g. is navigation using the keyboard shortcuts possible? Are keyboard shortcuts customizable?). Magnification handling is also a key usability parameter, and software should provide reliable support for standard magnifications (e.g. 10×, 20×, 40×) and consistent zoom behaviour.

Diagnostic support tools

Check whether the software provides tools to assist routine pathology tasks, including simultaneous visualisation of WSIs (to compare different stains or levels); taking measurements (e.g. besides linear measurements, is it possible to measure irregular shapes and areas?); mitotic counting (e.g. Does the DP system offer a way to easily assess mitoses? Some systems provide a grid with customizable areas to count mitosis; others allow drawing regions with specific dimensions); annotating (e.g. which annotation tools does the system offer? Are the tools easy and intuitive to work with?); and acquiring snapshots from regions of interest. It can also be relevant to consider whether the system allows for inserting (annotated) microscopic images into the diagnostic reports.

Conference and multi-user modes

Some software options may allow collaborative practice, facilitating case discussion, teaching, and consensus review, particularly in multidisciplinary meetings and remote diagnostic settings. Assess whether the system allows for synchronous and asynchronous teleconsultation.

External sharing

Support for external case sharing, with colleagues outside your institution, is particularly relevant in consultation workflows. It is often a limitation of current DP systems, as automated case de-identification and straightforward creation of external accesses are not provided by many available platforms. At any rate, attention to this functionality is recommended, as it can significantly influence the practicality of consulting with external partners. In this context, the availability of secure architectures, such as demilitarised zones, can be considered, as these enable controlled sharing while maintaining institutional network security.

Computational Pathology research

For departments active in Computational Pathology research, conduct a rigorous evaluation of the system's annotation suite and ensure that annotations are exported in standardised, machine learning (ML)-ready formats such as XML or JSON.

Infrastructure-related parameters

File and scanner compatibility

Ideally, the IMS should be agnostic and support all common WSI formats. At a minimum, it should reliably open and display WSIs from all scanners and file formats used (or planned to be used) in your institution. Depending on your institution, the IMS may also need to support file formats from other disciplines or modalities (e.g. radiology images, macroscopy photography, and immunofluorescence), as well as z-stacking capabilities for cytology or other purposes. If your department provides consultancy services, the possibility of importing and managing external case images should be checked.

Security and communication standard

Ensure security measures to guarantee data integrity across all phases of the process (storage, transmission, viewing). Regarding the communication standard, Health Level Seven (HL7, https://www.hl7.org/) is recommended, since it is a widely adopted protocol for the exchange of healthcare information between systems.

Effective storage management

Enabling seamless access to recent and archival cases has a significant impact on IMS performance and usability. Whether your department opts for on-premise, hybrid, or cloud-based storage solutions, integration with the LIS and/or IMS, and other laboratory systems is essential.

Input devices

Depending on institutional requirements, it may be relevant to assess whether the software is compatible with 3D mice or other specialised input devices [28]. Some devices might reduce repetitive strain, which is especially relevant in high-volume practices. This topic is further explored in the section 'Parameters to evaluate when acquiring DP workstations'.

Multisite management

For multisite deployments, the architectural considerations described in the section 'Parameters to evaluate when acquiring DP scanners – Infrastructure-related parameters' (e.g. centralised versus federated models) also apply.

Workflow support and AI-linked parameters

Case ordering and prioritisation

Some systems may allow cases to be organised and prioritised based on predefined criteria/preference worklists or by integrating AI to enhance prioritisation (e.g. AI models for automated triage of high-risk or tumour-likely cases that can feed into worklists for earlier review). Furthermore, case assignment, directing cases to the most appropriate pathologist, can also

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benefit from automation. Such systems may improve workflow efficiency and reduce turnaround times, and it could be valuable to assess whether the chosen viewing system or LIS includes these capabilities.

Integration with AI tools

This represents a growing evaluation dimension. It includes not only the availability of built-in AI functionalities but also the ease of integrating external AI solutions and managing AI outputs. It is important to evaluate whether the system allows incorporation of third-party AI models, as open systems provide greater flexibility, whereas closed systems may limit future expansion. It is also relevant to consider how AI integration is implemented in practice: some systems that support third-party AI may require the externalisation of slides to the AI provider's cloud, after which the resulting heatmaps and AI outputs are reintegrated into the IMS. Users may prefer full and seamless integration, rather than a workflow that relies on external processing, which could have implications for data security and workflow efficiency.

Other factors

Regulatory compliance

Regulatory requirements for DP software follow the same regional frameworks described in the section 'Parameters to evaluate when acquiring DP scanners – Other factors'. In the European context, EU IVDR compliance is essential for diagnostic use and may support laboratory accreditation [e.g. International Organization for Standardization (ISO) 15189]. Equivalent regulatory alignment should be ensured in other jurisdictions.

Cost and operational considerations

Cost considerations follow the TCO principles described in the section 'Parameters to evaluate when acquiring DP scanners – Other factors' with additional emphasis on software-specific factors such as software updates, maintenance, and user licenses. In addition, pricing evaluations should explicitly account for the number and complexity of required system integrations, such as integration with storage solutions, one or multiple scanners, the LIS, external Picture Archiving and Communication System (PACS) from other specialties (e.g. radiology), AI algorithm providers, or even regional or national electronic health record repositories.

Parameters to evaluate when acquiring DP workstations

An update of the pathologist's workstation hardware setup is necessary when implementing DP. Although reporting is already digital, the system requirements for WSI visualisation are more demanding. It is also worth considering the grossing workstation, as modifications may be necessary if remote working and collaboration between institutions are planned. The typical workstation configuration includes one computer, two displays, a mouse, and a keyboard. A webcam and headphones with a microphone may also be included, for video conferences as well as dictation.

Usability and infrastructure-related parameters

Computer requirements

Dedicated random access memory (RAM) (8–32 GB) is essential to visualising WSIs correctly. However, no standards exist for selecting computer processing unit (CPU) or RAM specifications, and modern mid-range gaming computers often meet the requirements [1,15]. Management of WSIs can be affected by several other parameters, including network connection, switches, and infrastructure elements [1]. Compatibility with LIS, network infrastructure, and remaining hardware needs to be assured. A dedicated graphics card is preferred to ensure smooth WSI visualisation and support multiple monitors.

Display requirements

The minimum requirements for monitors are still debated [15]. Most implementations use high-contrast monitors (≥1,000:1), high-resolution screens with appropriate brightness (∼300 cd/m^2), and validated colour accuracy. For this, a point-of-use quality assessment tool has been proposed [29] which tests colour accuracy and may help evaluate the suitability of a particular screen for digital diagnostics. Screen sizes typically range from 24 to 32 in. (60.96 to 81.28 cm) (diagonal). There is a trend towards larger display sizes with smaller pixel sizes, which allows for greater field of vision; however, objects appear smaller when the original maximum magnification is reached, and it requires more bandwidth to stream the image [5].

FDA-approved built-in solutions use medical-grade displays, which offer a higher colour depth of 10 or 12 bits per channel and auto-calibration to current light conditions for displaying images more accurately, as well as higher refresh rates to reduce eye strain [1,15,30,31]. Some published specifications on diagnostic screens are as follows: brightness ≥ 300 cd/m^2; contrast ratio > 1,000:1; colour gamut > 99% sRGB; colour temperature = D65 or similar; delta $E < 3$ or similar; display technology = in-plane switching [4]. Other displays could be compared side by side with medical-grade displays, and their suitability could be directly assessed by pathologists (note that certain accreditation frameworks may mandate the use of validated or medical-grade monitors for primary diagnostic reporting).

Input device requirements

Standard office equipment, mouse and keyboard, are often complemented by specialised devices (e.g. game mice, 3D mice, trackballs, specialised pathology devices, trackpads, and touch displays) [1,28,32] according to user preference. These devices are used to navigate

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slides more efficiently and must be supported by the viewing software [5]. Offering a selection of input devices, when possible in the procurement process, and having the pathologists pick their favourite works, in our experience, is better than selecting these in a small focus group. This way, all colleagues are involved in the process and are part of the change. DP acceptance increases when the whole team is involved.

Workflow support parameters

Grossing station requirements

The typical grossing station configuration includes one computer, one display, a mouse, and a keyboard, as well as a barcode scanner, a cassette printer, and a dictation system with or without speech recognition. Instruments for photographic documentation of the sample as received in the container, of the sample during grossing, and of the tissue included in the cassettes are recommended [1]. Again, full integration with LIS is necessary to print cassettes, capture gross examination pictures, and dictate or type macroscopic descriptions. Barcode scanners facilitate automated specimen tracking and help reduce transcription errors [5].

Other factors

Cost and operational considerations

As with other components, workstation acquisition requires evaluation beyond the initial purchase. While individual components – computers, monitors, and input devices – may appear modest in cost compared to scanners or storage infrastructure, their cumulative financial impact can be substantial, particularly in medium- to large-scale deployments. TCO may include graphics cards, medical-grade displays, hardware replacement cycles, and IT support. For multisite networks, standardisation of workstation configurations can facilitate maintenance and bulk procurement advantages, but coordinated refresh cycles should be anticipated. Additional features, such as adjustable desks or specialised input devices, may also be considered.

Parameters to evaluate when acquiring DP storage

As whole-slide imaging becomes routine for diagnostics, teaching, research, and AI-supported workflows, pathology laboratories must procure storage solutions that ensure long-term data integrity, rapid accessibility, and regulatory compliance. The following parameters provide a structured framework for evaluating storage systems before deployment.

Usability and infrastructure-related parameters

Data volume estimation and retention strategy

A fundamental first step is estimating expected data volumes and their projected growth. A single WSI typically ranges between 1 and 4 GB. A practical approach involves counting all slides from a representative day or week and scaling to yearly volumes. Accurate projections should incorporate 5- to 10-year growth horizons and account for retrospective digitisation and possible research-driven duplication. Storage planning must also define retention durations. While indefinite storage is technically feasible, most slides are accessed primarily within weeks of diagnosis, with only a minority retrieved later for clinical follow-up, medico-legal review, or research [33,34]. This usage pattern strongly supports tiered storage strategies, enabling cost control as digitisation expands.

Storage tiering and architecture

Implementing multi-tiered storage balances performance with cost efficiency [34,35]. Hot storage provides immediate access for active diagnostics, using fast solid-state drives (SSDs) with retention of days to weeks. Warm storage serves occasional access needs, utilising hard disk drives (HDDs) with moderate performance and retention of months to years. Cold storage prioritises cost minimisation for long-term archival storage, using tape libraries or deep archive cloud storage with retrieval times of hours to days. Automated lifecycle policies govern migration between tiers based on file longevity and access patterns.

Storage architectures vary by institutional needs. Network-Attached Storage (NAS) suits moderate deployments, while Storage Area Networks (SAN) or object-based systems optimise concurrent multi-user access. Cloud or hybrid architectures offer elasticity and geographic redundancy but introduce governance and bandwidth challenges [10]. Scalability should allow incremental expansion without downtime. Medical IT infrastructures must align with standards such as ISO/IEC 27001 or DIN EN 50600, and integrated hardware must also conform to these requirements.

Performance and network considerations

Storage responsiveness directly influences diagnostic efficiency. Slide-loading latency can significantly impact turnaround time when accessing multi-gigabyte WSI files. When possible, solutions should be benchmarked for read/write speeds, input/output operations per second, and sustained throughput under realistic workloads, including concurrent user access, automated scanning, AI inference, and remote viewing. Network infrastructure is critical: local networks should provide 10-Gigabit Ethernet or faster connectivity. For multisite deployments, content delivery networks or edge caching may be necessary [36]. If feasible, validation testing under clinical workload scenarios is recommended before deployment [37].

Data integrity and security

Storage platforms must guarantee integrity, reliability, and regulatory compliance. Integrity verification through checksums and cryptographic hashing (e.g. SHA-256) can detect corruption during transfer or long-term storage.

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Redundancy schemes such as Redundant Array of Independent Disks (RAID) configurations, geographic replication, or erasure coding help protect against media failures. Security requires encryption at rest and in transit, role-based access control, and comprehensive audit logging for traceability. General Data Protection Regulation (GDPR) compliance is mandatory in Europe, with equivalent frameworks in other regions.

Backup, recovery, and disaster preparedness

Beyond real-time data protection, robust backup and disaster recovery plans are important for long-term data stewardship. The 3-2-1 backup rule – three copies, two media types, one off-site – represents best practice for critical data protection. Cloud-based replication can enhance resilience but must be governed by data residency requirements and regulatory constraints. Regular validation of backup integrity ensures that archived data will remain accessible in the event of system failure or ransomware attacks.

Interoperability and standards compliance

To ensure that protected and backed-up data remain accessible over decades, regardless of vendor changes, storage systems should conform to open standards. DICOM adoption for WSI storage and metadata embedding facilitates interoperability between scanners, IMS, LIS, and AI applications [22,38]. Vendor-neutral archives prevent proprietary lock-in and enable seamless migration between platforms. HL7 or Fast Healthcare Interoperability Resources (FHIR) interfaces enable integration with broader electronic health record (EHR) infrastructures. Standards-based storage approaches future-proof DP archives, ensuring long-term portability of WSIs, metadata, and annotations essential for cross-platform collaboration and emerging computational pathology applications.

Compression strategies

With storage infrastructure addressed, attention should be given to optimising storage utilisation. Compression will become increasingly important as volume grows. Lossless compression (typically 3–10× reduction, highly variable by image content) preserves fidelity for primary archives; lossy compression (JPEG: 10–20×; JPEG 2000: 30–50×) may be suitable for warm or cold storage tiers but requires validation demonstrating non-inferiority in clinical applications [38]. Inadequate compression settings risk degrading diagnostic quality, so pathologists should be involved in compression-related decisions, as it may affect diagnostic accuracy. Institutions should establish validation protocols before deploying lossy compression and monitor compression developments for long-term planning [38].

Other factors

Cost and operational considerations

Storage represents a major cost driver in DP deployment [10,39]. TCO analysis must include initial hardware/licensing plus ongoing costs: energy, cooling, monitoring, IT support, maintenance, and hardware renewal cycles. Cloud solutions reduce upfront costs but incur monthly charges and data egress fees. If possible, model on-premises, hybrid, and cloud scenarios. In parallel, energy-efficient and environmentally sustainable storage practices are increasingly relevant under hospital-wide carbon reduction policies, making energy consumption and cooling requirements relevant evaluation parameters beyond their direct cost implications. Storage tiering significantly reduces TCO by allocating expensive high-performance storage only where diagnostically required.

Parameters to consider for LIS in DP deployment

The LIS represents the backbone of modern pathology laboratories. Also known as anatomic pathology LIS (APLIS) or laboratory information management systems (LIMS), this software plays a central role in the digital transition. While the relevance of the LIS has already been emphasised by previously published ESDIP recommendations on the implementation of the digital workflow [15], and some tools/assessment methods exist for the evaluation of basic LIS functionalities [40], the dynamic changes experienced in recent years require an integrated and far-sighted solution that can satisfy the specific needs of the lab in terms of usability, workflow orchestration, and long-term strategic sustainability.

Usability parameters

Role-based access control (RBAC)

Modern pathology laboratories are based on a strong interplay among different professionals, ranging from pathologists and biomedical scientists/lab technicians to administrative staff and IT specialists. This interdisciplinarity further highlights the need for modern LIS to provide a user-friendly and efficient interface, incorporating RBAC, specifically designed for different users [41]. While RBAC allows the configuration of role-oriented dashboards and views to highlight task-oriented information, it also prevents potential errors and facilitates adherence to data protection regulations.

Remote accessibility

Remote accessibility is gaining increasing relevance for both flexible working models and telepathology allowance and may be further enhanced by the adoption of browser-based LIS solutions [41]. Through secure and device-independent access, these web-based systems are characterised by easier updates and seamless integration across distributed teams while allowing case review, collaboration, and decision-making without being physically present in the laboratory.

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Structured reporting

Structured reporting with customisable diagnostic templates with support for implementing synoptic reporting models is a desirable feature of a modern LIS. It allows for the reduction of the reporting phase while ensuring standardisation, completeness, and reuse of the diagnostic information [42]. This process is expected to be increasingly supported by large language models [43], which assist pathologists in structuring reports and applying standardised coding systems (e.g. SNOMED-CT) [44]. Moreover, the possibility of integrating different multimedia sources (e.g. macroscopic or microscopic images, WSIs, and annotations) can further enhance the final content of diagnostic reports.

Guided data entry

Checklists, step-by-step interfaces, and contextual alerts are a prerequisite for modern LISs, allowing for the standardisation of procedures, compliance with quality standards, rapid retrieval, and intuitive navigation among current/historical cases, facilitating access to large volumes of data in the digital transition.

Advanced usability features

Features such as voice recognition [45] and virtual/augmented reality implementation [46] are optional but may further improve the user experience, especially in specific settings, such as grossing station and microscopic reporting. This may reduce manual transcription, providing advanced multimedia documentation of these delicate phases, as reflected by both LIS assessment frameworks and real-world experiences [40,41].

Infrastructure-related parameters

Interoperability

Interoperability with HISs and EHRs/personal health records (PHRs) is an essential prerequisite to guarantee continuity of care and data consistency, with ancillary integrations (e.g. with endoscopic or radiology information systems) considered desirable features [47]. The adoption of internationally recognised data exchange standards, as described in previous sections, and the compliance with Integrating the Healthcare Enterprise (IHE) profiles, is unanimously recognised as a mandatory requirement for sustainable DP deployment [48].

Scalability

A modular design of the infrastructure may help accommodate the needs of different laboratories based on their size, complexity, and case mix, allowing the adaptation to small regional facilities and large hub–spoke networks. Moreover, the ability to support both on-premise and cloud-based deployments is essential to complying with the different needs of institutions in terms of local IT policies, financial constraints, and data governance strategies.

Security

This is a fundamental requirement for modern LIS, with RBAC, strong authentication mechanisms (e.g. multifactor authentication), data encryption both in transit and at rest, and comprehensive audit trails, which are essential to protecting sensitive patient information. These features are explicitly required by data protection regulations (e.g. GDPR) and accreditation standards (e.g. ISO 15189 [49]), with which pathology laboratories must comply.

Workflow support and AI-linked parameters

Entire workflow coverage

The workflow spans from sample collection to final reporting and archiving, reflecting the specimen-driven nature of the pathology laboratory practice. This should ensure full coverage of all phases, with traceability of samples through system logs and dashboards, enabled by the integration of barcode/radio-frequency identification (RFID)-based identification [50,51].

WSI and AI tools integration

The integration of WSI and AI tools has become a defining feature of modern LISs in the DP era. This integration may involve embedded image viewers (e.g. customised OpenSlide-based solutions), dedicated IMS (as described in the section 'Parameters to evaluate when acquiring DP software'), or external providers such as AI-tool vendors offering multiple solutions [15]. Regardless of the specific approach, essential requirements include bidirectional case--image linkage, seamless WSI visualisation to ensure an optimal user experience, and AI-ready IMS options capable of managing algorithm outputs and annotations with structured, auditable storage of derived data [47].

Built-in quality checks and automation support

These are increasingly essential in enabling a fully DP workflow. In this context, seamless integration across all molecular pathology steps (from nucleic acid extraction to final reporting and data storage based on cyto-histological samples) is becoming critical, given the growing volume of such examinations. The adoption of automated solutions within pathology departments further requires tighter integration with LISs, incorporating quality controls that position LISs as orchestrators of laboratory innovation [52,53]. In addition, embedded alerts for inconsistencies and workflow checkpoints can help reduce diagnostic errors and strengthen process robustness. Looking ahead, the integration of agentic AI and digital twin concepts may further enhance inventory and reagent management, reduce waste from expired materials, shorten turnaround times, and improve diagnostic accuracy [53].

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Other factors

Long-term sustainability and guideline alignment

These are strategic considerations when acquiring a new LIS, particularly in light of the exponential growth of WSI data, the need for scalable storage, and rapid technological advances that continuously reshape DP tools. Ongoing compliance with professional guidelines [19] and recommendations from scientific societies [15] is essential to ensuring that LISs remain compliant with and capable of supporting future developments, including advanced AI-driven diagnostics.

Cost

The cost of a LIS can vary significantly based on different factors. Commercial, ready-to-use systems from established vendors typically involve higher upfront and recurring costs but provide proven deployments, regulatory compliance, and standardised interoperability with HISs and laboratory hardware [40]. Conversely, home-made or regionally developed solutions [5] may lower licensing expenses but often transfer costs to long-term internal development, validation, maintenance, and reliance on local IT expertise, with increased risks related to scalability and regulatory alignment [41]. Importantly, additional long-term costs, such as service agreements, system integrations, access to updates, regulatory adaptations, and structured user training, should be explicitly considered during procurement.

Conclusions

The pre-deployment evaluation of DP systems represents a decisive step in ensuring future-ready digital transformation within pathology laboratories. As emphasised throughout this ESDIP guide, procurement decisions must extend beyond vendor specifications and acquisition costs, incorporating context-aware assessment of scanners, software, workstations, storage infrastructures, and LIS integration. Evaluation strategies should be tailored to the deployment context. Large-scale multisite and public tenders benefit from real-world stress testing under routine-like workload conditions. In contrast, single-site and private institutions, operating under practical constraints, should adopt more focused assessment approaches. Across all settings, alignment with the institutional scope (encompassing slide volume, integration requirements, long-term archiving strategy, and financial sustainability) is fundamental. Ultimately, DP acquisition should be regarded not as a discrete hardware or software purchase but as a strategic institutional transformation. A structured and forward-looking evaluation process, as outlined herein, is critical to ensuring that DP platforms support diagnostic quality and long-term innovation in modern pathology practice.

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Author contributions statement

DM and JT-S conceived and designed the study. DM, VI, DA, RC, PB, SPO, NK and JT-S conducted literature searches and drafted the different sections of the manuscript. NZ and IZ reviewed and revised the paper. All authors read and approved the final manuscript.

Data availability statement

Data sharing is not applicable as the article derives from the authors' practical experience and literature review. Supporting data are provided in the supplementary files.

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SUPPLEMENTARY MATERIAL ONLINE

Table S1. Checklist to evaluate DP scanners

Table S2. Checklist to evaluate DP WSI viewers/image management systems

Table S3. Parameters to evaluate when acquiring DP workstations

Table S4. Checklist to evaluate when acquiring DP storage

Table S5. Checklist to evaluate LISs

File S1. Summary of award criteria breakdown

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