PHILIPS

Digital Pathology

FAQ leaflet

DICOM in digital pathology

Achieve seamless scanner integration with vendor-agnostic interoperability

Fulfill your pathology requirements now and into the future with Philips pathology solution. The DICOM® image format supports efficient exchange of image data and associated metadata for seamless integration into your lab's infrastructure.

What is DICOM file format for digital pathology?

Digital Imaging and Communications in Medicine (DICOM) is the international standard for medical images and related patient information. Originally developed for radiology, DICOM was recently adopted for other medical domains - including digital pathology - to promote standardization and interoperability between systems.

Philips strongly supports standardization and is a member of Working Group 26, which is tasked to support, develop and test DICOM standards for whole slide images (WSIs). Philips contributed to Supplements 145 and 122 for WSI. In addition, Philips is a member of the Digital Pathology Association (DPA) Regulatory and Standard Task Force.

What are the benefits of implementing DICOM and why is it necessary?

The DICOM standard will allow seamless integration of digital pathology scanners with viewers, AI applications, PACS and VNAs from different vendors. This will also support cross-modality collaboration between pathology and other imaging modalities to empower integrated diagnostics and decision-making. While it is still possible to share proprietary WSIs between systems. Without DICOM, all vendors would need to adapt their system to work with each unique proprietary file format. Philips has been and will continue to support this with a public Software Development Kit (SDK) and a free iSyntax File Viewer[1].

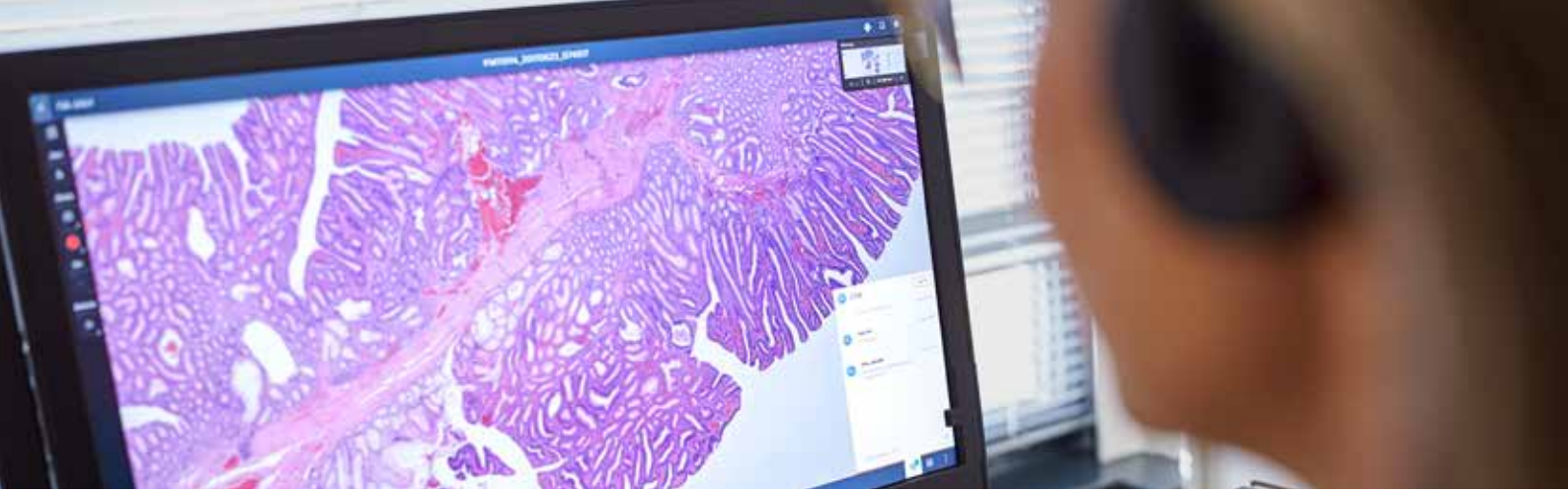
Why do not all digital pathology vendors have a DICOM file format?

Philips was the world's first vendor to release an IVD-labeled digital pathology system (both CE-IVD in 2013 and an FDA De Novo clearance in 2017). This required close collaboration with regulators to set up a new regulatory framework to be used by the rest of the industry. Since digital pathology is a relatively new digital imaging modality compared to radiology and other modalities, there was no DICOM standard, and all digital pathology vendors have developed their own proprietary format. No labs currently use DICOM images exclusively on an end-to-end digital pathology solution for primary diagnosis.

What are the challenges with implementing DICOM standard for whole slide images (WSIs)?

The DICOM standard is intended to realize interoperability between scanners, viewers, and other pathology systems. Regulators (such as the U.S. Food and Drug Administration) require a closed end-to-end system consisting of a scanner, image viewer and monitor, to be tested as one entity. Therefore, it remains a challenge for vendors to introduce an open ecosystem that allows interoperability while at the same time remaining compliant with regulatory requirements.

Additionally, a typical DICOM file contains patient and study/case information. Because DICOM follows the radiology context, this data is known already during the image acquisition. However, in the digital pathology workflow, this is not the case since scans can be made without upfront patient



or study/case information. A standalone digital pathology scanner cannot read DICOM data, thus specific software is needed to read and produce a complete DICOM file with study/data from a laboratory information system (LIS). Working Group 26 is still discussing a solution for this.

Not all PACS/VNAs are ready to support WSIs due to the unique attributes and file size. Philips intends to integrate the PACS/VNA into its digital pathology solution.

How has Philips implemented the DICOM standard for WSIs?

Philips enables a DICOM export that converts its iSyntax format to a lossless, DICOM-compliant JPEG2000 file.[1] Philips DICOM files have proven successful during the DICOM Connectathons in the last seven years. We successfully tested an improved DICOM export during the 2023 Connectathon. More information can be found in the Philips IntelliSite Pathology Solution DICOM Conformance Statement that includes detailed information on DICOM files.[1]

What is the future of DICOM for digital pathology at Philips?

To ensure an open ecosystem for digital pathology without compromising quality, safety, and digital pathology capabilities, Philips will continue to improve and adapt the DICOM export as the standard emerges.

Going forward, Philips intends to support both DICOM and iSyntax file formats, for the Philips IntelliSite Pathology Solution[2]. This ensures a versatile solution to fulfill current and future pathology requirements so that interoperability will not be a concern for existing and new users. Philips will remain an active member of Working Group 26 to develop, test and adopt the best-suited standard for WSI Slides.

If you have specific questions related to DICOM, please contact your local Philips sales representative.

www.philips.com/digitalpathology

Philips IntelliSite Pathology Solution (PIPS) can be used for in vitro diagnostic purposes. The system can aid pathologists to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue. PIPS is not available for sale in all countries.

PIPS enables iSyntax files with SDK, third party companies can use this for AI capabilities.

1 The Software Development Kit (SDK) and File Viewer is not intended for diagnostic, monitoring or therapeutic purposes or in any other manner for regular medical practice.

2 The Philips Digital Pathology solution is a bundle of: Pathology Scanner Second Generation SG20/ SG60/ SG300 • Image Management System Viewer • Image Management System Application Server and Storage Software • High quality 27" monitor validated with the IVD solution (US only)

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How to reach us
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