U.S. FOOD & DRUG ADMINISTRATION

Guidance Snapshot

Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers

Final Guidance for Industry

What is Covered in this guidance?

This guidance provides information to sponsors and nonclinical laboratories regarding the use and management of whole slide images used during histopathology assessment and/or pathology peer review performed for good laboratory practice (GLP)-compliant nonclinical toxicology studies.

Why is this Guidance important?

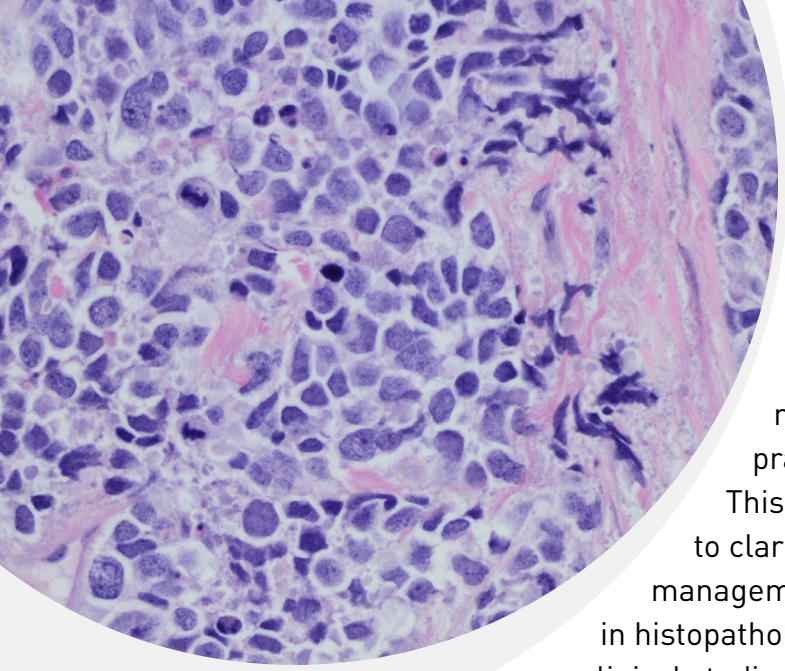
The histopathological assessment of tissue samples is one of the key activities conducted during GLP-compliant nonclinical laboratory studies. Commonly, the histopathological assessment includes an initial evaluation of glass histology slides by the study pathologist and a subsequent review (referred to as pathology peer review) by a second pathologist, group of pathologists, or Pathology Working Group. When whole slide imaging is used as part of a nonclinical study conducted in compliance with the GLP regulations, the management, documentation, and use of whole slide images in histopathology assessment and/or pathology peer review should be clear and follow written processes and procedures.

What Is Addressed in this Guidance?

Among the topics addressed in this guidance:

- Whether whole slide images should be retained.
- Whether written procedures for whole slide imaging processes should be in place.
- Whether the whole slide imaging system should be validated.

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about whole slide imaging in nonclinical toxicology studies, read the guidance.

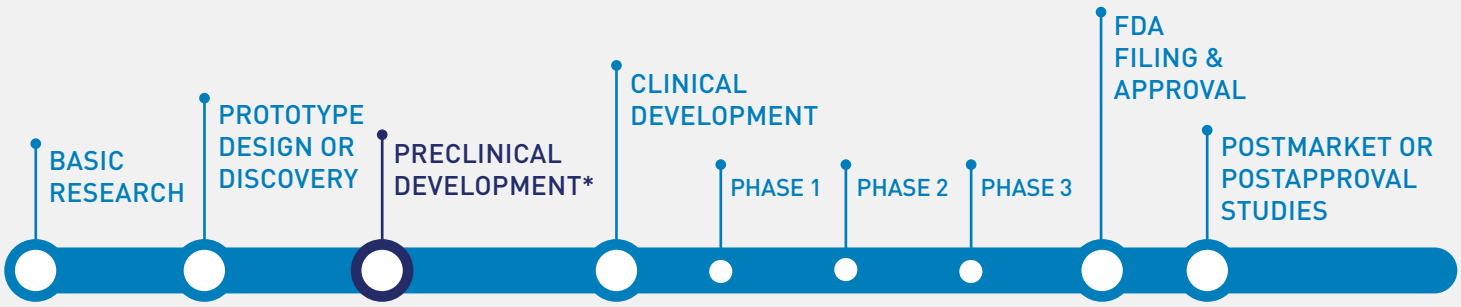


Background About the Guidance

This guidance finalizes draft guidance issued in April 2022 titled Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers. The FDA's expectations regarding documentation practices during generation, use, and retention of whole slide images have not been clearly defined, and thus, documentation practices vary among nonclinical testing facilities. This question-and-answer document is intended to clarify FDA's recommendations concerning the management, documentation, and use of whole slide imaging in histopathology assessment and/or pathology peer review for nonclinical studies conducted in compliance with the GLP regulations.

Drug Development Timeline

*** When to Apply the Guidance Recommendations**



During Preclinical Development: This guidance provides information regarding the use and management of whole slide images used during histopathology assessment and/or pathology peer review performed for good laboratory practice (GLP)-compliant nonclinical toxicology studies using non-human specimens. The guidance does not cover the use of whole slide imaging for clinical applications.

Guidance Recap Podcast

Hear highlights from FDA staff

Speaker(s): Lynda Lanning, DVM, DABT, Toxicologic Pathologist in the Center for Drug Evaluation and Research's Office of Study Integrity and Surveillance

Click here to listen

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Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about whole slide imaging in nonclinical toxicology studies, **read the guidance**. To see additional Guidance Snapshots, **check out the pilot program**.