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HISTOPATHOLOGY – FROM SUPPORTIVE TO DOMINANT TOOL IN PRECLINICAL EFFICACY STUDIES

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The histopathological evaluation in preclinical efficacy studies is often biased due to unsuitable methods, lack of standardization and use of qualitative observations. A comparison between studies is difficult because of the diversity of assays used to assess a similar tissue and injury. In addition, the need for a specifically trained expert to analyze the histological data also leads to the lesser use of histology in the R&D of drug development. The aim of this presentation is to demonstrate the contribution of quantitative measures and advanced image analysis tools to seek for an unbiased histopathological evaluation. By choosing the most relevant parameters, that best suit the scientific questions being addressed, investigators may overcome the risk of incorrect interpretation. Examples of a quantitative assessment of multiple histological features for various injuries will be shown, indicating the advantages of using a computerized image analysis system for densitometry and for morphometric analysis. The latter is critical for the assessment of the extent of tissue injury in efficacy studies in experimental animal models. Attention will be drawn to lung tissue and free-floating brain sections. Quality assurance measures support the histopathological analysis, contributing to the reduction of errors and to the ability to detect subtle differences between treatment groups. In summary, the scientific impact of histopathology in preclinical efficacy studies at present, is increasing and becoming dominant due to the greater use of advanced methodology and quantitative analysis.