INHAND: International Harmonization of Nomenclature and Diagnostic Criteria for Lesions - An Update - 2019

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Background:

Harmonization of nomenclature and diagnostic criteria in toxicologic pathology has been a goal of pathologists working in the profession for many years. Early initiatives were undertaken by the STP in the United States and by the RITA data base group (Registry of Industrial Toxicology Animal-data) in Europe. Their efforts resulted in a number of internationally recognized publications: SSNDC: Guides for Toxicologic Pathology and the WHO/IARC International Classification of Rodent Tumors. In 2005, the STP and European Society of Toxicologic Pathology (ESTP), in conjunction with RITA, developed a collaborative process to review, update, and harmonize existing nomenclature documents and databases. In 2006, the British Society of Toxicologic Pathology (BSTP) and the Japanese Society of Toxicologic Pathology (JSTP) joined the initiative, so that the project has become truly global.

Objectives:

•Produce publications for each rodent organ system and select non-rodent species that provide a standardized nomenclature and differential diagnosis for classifying microscopic lesions observed in toxicity and carcinogenicity studies

New Mission:

•Serve in advisory role for the FDA Standard for the Exchange of Nonclinical Data (SEND) initiative. FDA has indicated a preference to utilize microscopic pathology terminology developed by INHAND as these terms will be published in a peer-reviewed journal.

•Two representatives from GESC sit on the SEND Controlled Terminology Team to assist with mapping INHAND terminology to SEND codelists of preferred terms and reviewing requests for new terms.

Structure

•Global Executive Steering Committee (GESC) with representation from major societies of toxicologic pathology

•15 organ system working groups (OWG) defined by GESC

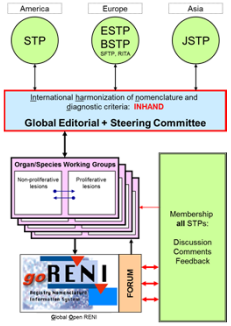
Structure

•5 non-rodent species working groups: dog, monkey, minipig, rabbit and fish

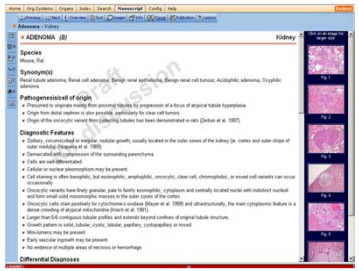
•New group formed to address terminology in non-rodent ocular toxicity studies

•Each group is composed of expert toxicologic pathologists from each of the participating societies responsible for developing preferred nomenclature and diagnostic criteria.

Diagram of INHAND Structure and Process



- WG develop nomenclature primarily descriptive in nature and denote findings which can be documented from the review of routine histologic specimens.
- Incorporating diagnoses that imply a process that cannot be determined from routine histologic specimens (e.g. phospholipidosis) is not recommended.
- Upon completion of the draft nomenclature, GESC conducts an initial review, followed by a period during which all members of participating societies are requested to review the proposed nomenclature.
- WG then finalizes the nomenclature based on comments from the GESC and general membership.
- Published diagnoses may be extended or amended; a change control process is now available.
- An important feature of INHAND is the use of the goRENI (global open Registry Nomenclature Information System, www.goreni.org) as a web-based platform to both review draft nomenclature and publish final nomenclature. Originally developed by RITA, goRENI provides access to members of all STPs as well as government regulators. **The most current version of nomenclature is available on goRENI.**



Completed Organ Systems:

- Respiratory System (Toxicol Pathol. 37 (7 Suppl):5S-73S)
- Hepatobiliary System (Toxicol Pathol. 38(7 Suppl): 5S-81S)
- Urinary System (Toxicol Pathol. 40 (4 Suppl): 14S-86S)
- CNS/PNS System (Toxicol Pathol. 40 (4 Suppl): 87S-157S)
- Mammary, Zymbal's, Preputial and Clitoral Glands (Toxicol Pathol. 40(6 Suppl): 7S-39S)
- Male Reproductive (Toxicol Pathol. 40(6 Suppl): 40S-121S)
- Soft Tissue (J Toxicol Pathol. 26 (3 Suppl): 1S-26S)
- Integument (J Toxicol Pathol. 26 (3 Suppl): 27S-57S)
- Female Reproductive (J Toxicol Pathol. 27 (3&4 Suppl): 1S–107S)
- Digestive System (J Toxicol Pathol. 29 (1 Suppl): 1S–124S)
- Recommendations from the Apoptosis/Necrosis Working Group (Toxicol Pathol. 44(2), pp173-188)
- Cardiovascular System (J Toxicol Pathol. 29 (3 Suppl): 1S–47S)
- Skeletal System (J Toxicol Pathol. 29 (3 Suppl): 49S–103S)
- Endocrine System (J Toxicol Pathol. 31 (3 Suppl): 1S–95S)
- Special Senses (J Toxicol Pathol. 31 (3 Suppl): 97S–214S)

In Progress:

•Lymphoid and Hematopoietic System (ready for publication)

•Non-rodent

Acknowledgements

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