The New Nomenclature Project

INHAND

International Harmonization of Nomenclature and Diagnostic Criteria for Lesions in Rats and Mice
INHAND Historical Background

**Literature**

- **1983-1991**  Monographs on Pathology in Laboratory Animals, ILSI
- **1990** Pathology of Tumours in Laboratory Animals: Volume 1 – Tumours of the Rat, IARC
- **1994** Pathology of Tumours in Laboratory Animals: Volume 2 – Tumours of the Mouse, IARC
- **1996** Pathology of Tumours in Laboratory Animals: Volume 3 – Tumours of the Hamster, IARC
- **1996–2001** Monographs on Pathology in Laboratory Animals (2nd Edition), ILSI
- **1990** Pathology of the Fischer Rat, NTP, Boorman et al.
- **1990–2003** SSNDC Guides, STP/ARP/AFIP (31 Volumes)

IARC = International Agency for Research on Cancer
INHAND Historical Background

Revision of Nomenclature

- 2001 RITA started with revision of rat manuscripts under consideration of harmonized rat nomenclature
- 2005 STP discussed revision and extension of SSNDC guides primarily for non-proliferative lesions
- 2005 INHAND proposal brought forward by ESTP and RITA for STP consideration
- 2006, the BSTP and the JSTP joined the initiative, so that the project was truly global
INHAND organization

- STP
- ESTP/BSTP/SFTP, RITA
- JSTP

International harmonization of nomenclature and diagnostic criteria: INHAND

Global Editorial + Steering Committee

Organ/Species Working Groups

- Non-proliferative lesions
- Proliferative lesions

Membership of all STPs:
- Discussion
- Comments
- Feedback

Registry Nomenclature Information System

GoRENI

Global Open RENI
INHAND Nomenclature

- 15 organ system working groups and 4 non-rodent species working groups defined by GESC
- Terminology proposal by GESC based on
  - SSNDC for non-proliferative and
  - RITA/WHO/IARC and
  - Terminology of “International Harmonization of Rat Nomenclature” for proliferative lesions
  - Literature reviews as appropriate
- Will be discussed by working groups and may be extended/amended
- In general, the working groups should develop nomenclature that is primarily descriptive in nature and denote findings which can be documented from the review of routine histologic specimens. Incorporating specific diagnostic entities such as an infectious disease or that imply a process that cannot be ascertained from routine histologic specimens (e.g. phospholipidosis) is not recommended
INHAND Manuscripts

- Members of each Society are notified that the draft is posted and available for comments for a 60 day period. After the comment period is completed, the WG considers comments and prepares a final draft. This final draft is reviewed once more by the GESC and posted on goRENI.

- In addition to posting on goRENI completed nomenclature for each organ system will be published in the official journals of the participating Societies: Toxicologic Pathology (STP and BTP), Journal of Toxicologic Pathology (JSTP) or Experimental and Toxicologic Pathology (ESTP)

- Current status (as of January 2013):
  - Respiratory System complete and published in Toxicologic Pathology
  - Hepatobiliary System complete and published in Toxicologic Pathology
  - General Principles manuscript complete and published in Toxicologic Pathology
  - Urinary system complete and published in Toxicologic Pathology
  - Central Nervous System and Peripheral Nervous System complete and published in Toxicologic Pathology
  - Male Reproductive System complete and published in Toxicologic Pathology
  - Mammary Gland, Zymbals Gland and Clitoral/Preputial Gland complete and published in Toxicologic Pathology
  - Other organ systems in various stages of drafting

INHAND Collaboration with FDA

**How will this impact the (anatomic) pathologist?**

- Microscopic findings automatically mapped (bucketed) into base processes (e.g. degeneration, necrosis, inflammation, hyperplasia) by SEND-compliant software
  - Vendor-supplied SEND-compliant modules
  - Sponsor-developed proprietary software

- Published INHAND microscopic diagnoses are used as the basis for the standardized terminology
  - Being mapped into appropriate base processes and modifiers to provide controlled terminology lists
  - Mapped lists of terms will be used by software that converts pathology data into the standardized format for FDA submission
Questions?

INHAND Global Editorial Steering Committee (GESC)

- **STP**
  - Charlotte Keenan (chair)
  - Peter Mann (previous chair)
  - John Vahle (previous chair)
  - Ron Herbert
  - Dawn Goodman

- **BSTP**
  - Alys Bradley
  - Julia Baker

- **ESTP**
  - Suzanne Rittinghausen
  - Wolfgang Kaufmann
  - Thomas Nolte

- **JSTP**
  - Takuji Tanaka
  - Takanori Harada

- **Fraunhofer**
  - Gerd Morawietz (retired)
  - Rupert Kellner

- **Beth Mahler, NTP**
InHAND Special Senses Working Group (active members)

- Julia Baker, Charles River Pathology Associates, GESC Liaison/Chair
- Elke Atzpodien, Roche
- Ute Bach, Bayer HealthCare Pharmaceuticals
- James Cartwright, Huntingdon Life Sciences
- Cindy Fishman, GlaxoSmithKline
- Matthew Jacobsen, AstraZeneca
- Ursula Junker-Walker, Novartis
- Frieke Kuper, Netherlands Organization for Applied Scientific Research
- Maria Cecilia Rey-Moreno, BSAF
- Jim Render, NAMSA
- Susanne Rittinghausen, Fraunhofer Institute for Toxicology and Expt Medicine
- Ken Schafer, Vet Path Services
- Brian Short, Allergan
- Koji Tanaka, Boehringer-Ingelheim
- Leandro Teixeira, OSOD / COPLOW / University of Wisconsin
- Katsu Yoshizawa, Kansai Medical University / Takii Hospital
Nonproliferative Lesions of the Eye and Adnexa

- Introduction
  - Overview
  - Ocular Morphology
  - Ocular Embryology and Congenital Malformations
  - Approach to Microscopic Evaluation of Ocular Tissues

- Nomenclature
  - General Pathology
  - Adaptive Changes
  - Iatrogenic/Injury
  - Healing Response
  - Infiltrate (Inflammatory cells)
  - Inflammation
  - Eyelid, Conjunctiva, Cornea, Sclera, Filtration angle/Trabecular meshwork, Uvea, Lens, Vitreous, Retina, Optic nerve, Harderian gland, Nasolacrimal duct, Lacrimal gland, Olfactory System, Otic System

- Proliferative Lesions