

ANNOUNCING INHAND CHANGE CONTROL

The INHAND Project (International Harmonization of Nomenclature and Diagnostic Criteria for Lesions) is a joint initiative of the STP, ESTP, BSTP and JSTP to develop an internationally-accepted nomenclature for proliferative and non-proliferative lesions in laboratory animals. An Organ Working Group (OWG) comprised of experts in that organ system prepares draft nomenclature for both proliferative and non-proliferative lesions of the rat and mouse. Non-rodent Working Groups (NRWG) are comprised of experts in non-rodent species, specifically the dog, monkey, minipig and rabbit. Prior to finalization, proposed nomenclature for each organ system or species will be posted on the goRENI website (www.goreni.org) for comments from members from any of the participating societies.

The INHAND nomenclature is being adopted by the FDA for use in the SEND initiative (Standard for the Exchange of Non-clinical Data), and as such we anticipate that the INHAND nomenclature will be widely accepted by companies and other regulatory agencies.

Pathologists who discover a lesion in a toxicity study that is not covered by the INHAND nomenclature (www.goreni.org) are encouraged to request a new INHAND term. In addition, changes, additions, and updates to current terms may be desirable and may be requested as well.

For a most efficient process it is mandatory that the submitting pathologist provides a precise description of the lesion in question. This description should meet the INHAND format and should consider the general INHAND principles (Mann PC et al. 2012). A bullet point style is recommended. A respective template is provided below which should be completed thoroughly. The request will be reviewed by the INHAND Global Editorial and Steering Committee (GESC) and the respective Organ Working Group (OWG) or Non-rodent Working Group. GESC and OWG/NRWG will decide on the request in a timely manner. If there is a delay, the submitter will be informed and be kept apprised of progress on the request. The GESC will accept without modification, accept with suggestion of modification, or reject. Once accepted, the new term will be added to the INHAND nomenclature. This new term will also be communicated to SEND by periodic update and in this way will be added to the recommended SEND-nomenclature. It will, therefore, facilitate later submission processes to FDA.

Categories for change requested:

- **New term with new description**
- **Additional organs/topography for published INHAND term**
- **Change of published term**
- **Change of/addition to published description**
- **Additional synonym for published term**
- **Addition of new photograph(s) for published INHAND term**
- **Deletions**

Forms for these types of requests can be found on www.goreni.org and on Society web sites.

Completed forms should be emailed to Rupert Kellner, rupert.kellner@item.fraunhofer.de

All members of the STP, ESTP, BSTP or JSTP have access to the goRENI website. Once you have logged into the goRENI system, you can navigate to the change control forms. For further directions on how to

use goRENI, please visit www.goreni.org or <http://www.toxpath.org/inhand.asp>.

If you need assistance with access to the goRENI system, please contact Rupert Kellner (rupert.kellner@item.fraunhofer.de).

If you have comments you would like to convey directly to the GESC, please contact any of the GESC members:

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