

Summary of Standard Operating Procedures

Purpose

This SOP outlines the responsibilities and procedures by which the INHAND Global Editorial and Steering Committee (GESC) functions. The primary charge of the INHAND GESC Committee is coordination of agreement on a systematized terminology / nomenclature for non-proliferative and proliferative microscopic lesions in rodents (rats, mice) and non-rodents (dog, monkey, mini-pig, rabbit). The GESC also advises the Standard for Exchange of Nonclinical Data (SEND) of the U.S. Food and Drug Administration (FDA) on microscopic pathology terms. The organization of the GESC and Working Groups is provided in the attached figure.

While this committee entails participation of several global societies, administrative infrastructure will be coordinated through the STP.

GESC Responsibilities

The Committee will:

Function as a permanent GESC responsible for:

- Discuss and agreed on a systematized terminology / nomenclature for non-proliferative and proliferative lesions in rodents (rats, mice) and non-rodents (dog, monkey, mini-pig, rabbit).
- Define a common format for the presentation and structure of manuscripts.
- Establish working groups and select members.
- Review the proposed terminology with the organ or species working groups prior to publication.
- Involve the leadership and membership of the sponsoring societies (British Society of Toxicologic Pathologists, the European Society of Toxicologic Pathology, the Japanese Society of Toxicologic Pathology and the Society of Toxicologic Pathology, abbreviated BSTP, ESTP, JSTP, and STP, respectively) in the review and approval for the proposed systematic terminology.
- Review final draft versions of the manuscripts.
- Approve publication of manuscripts and ensure maintenance of updated information on websites (goreni and Society websites).
- Review and approve change control requests
- Serve as an advisory group concerning microscopic pathology terminology for the Standard for Exchange of Nonclinical Data (SEND).
- Conduct business on a regular basis via email, conference calls, and a face-to-face meeting during annual meetings of one or more sponsoring societies. Meetings will be scheduled by the GESC chair as needed
- Coordinate with other societal committees regarding shared activities and interests
- Communicate regularly with the leadership of the sponsoring societies.

Committee Membership

The Committee will consist of the following:

- Chair
- Members at large
- Sub committees
- Observers

Specific Roles and Duties

Chair

This individual will:

- Serve a 3 yr. term. The GESC may extend the term of a chair at its discretion. The Chair with the GESC will select an individual from the GESC to succeed the chair with suitable time for transition.
- Provide leadership, guidance, and direction to the committee
- Be responsible for regular meetings during the year with agenda and minutes to accomplish all committee responsibilities
- Provide sponsoring societies with an annual written report of INHAND activities for the prior year and other reports as requested
- Provide an annual budget projection to the sponsoring societies including estimated teleconference costs for the GESC and working groups, face-to-face meeting expenses, and goren services. The number of publications expected in the coming year should be identified, but publication cost estimates are not required.
- Provide orientation and training for new members.

Members-at-large

These individuals will:

- Be recruited for balance and diversity within the committee, 9 to 12 individuals who represent BSTP, ESTP, JSTP, and STP. The members are nominated or elected by the sponsoring societies.
- Serve a 3 year term (extensions to the three-year member limit may be approved by the sponsoring society and the GESC)
- Assist the committee with its general responsibilities
- Communicate views and comments of the sponsoring societies to the GESC.

Observers from Other Toxicologic Pathology Societies

This individual will:

- Be appointed by each non-voting society
- Attend and participate in committee meetings and teleconferences at the discretion of the observer
- Receive copies of GESC agendas, minutes, and reports
- Bring INHAND questions and concerns to the sponsoring societies, as appropriate
Communicate concerns, decisions or assigned duties from supporting societies to the GESC

Subcommittees – Organ or Species Working Groups

Working group members are selected by the GESC to represent geographic diversity, views of the sponsoring societies, and subject matter expertise.

Duties of the Working Group Chair

- Appointed by the GESC
- Organizes the group
- Conducts business, preferably by teleconference and e-mail
- Assigns tasks to members, e.g., responsibilities for specific organs or species
- Coordinates the flow of information between the sub-groups for non-proliferative and proliferative lesions
- Manages time lines for publication
- Ensures high quality development, review, editing, and publishing of working group recommendations in conformance with instructions to authors.
- Serves as expert for questions from the GESC concerning terminology in SEND; convenes working group members as needed for discussion

Duties of a Working Group

- Drafts document describing proliferative and non-proliferative lesions for rodents and non-rodents.
- Members provide images in order to illustrate all lesions if feasible.
- Provides final draft within approx. 1-2 years.

- Format manuscripts for publication
- Review and revise nomenclature, definitions, diagnostic criteria, and images for specific topics as directed by the GESC.

Process for Appointing New Working Group Members

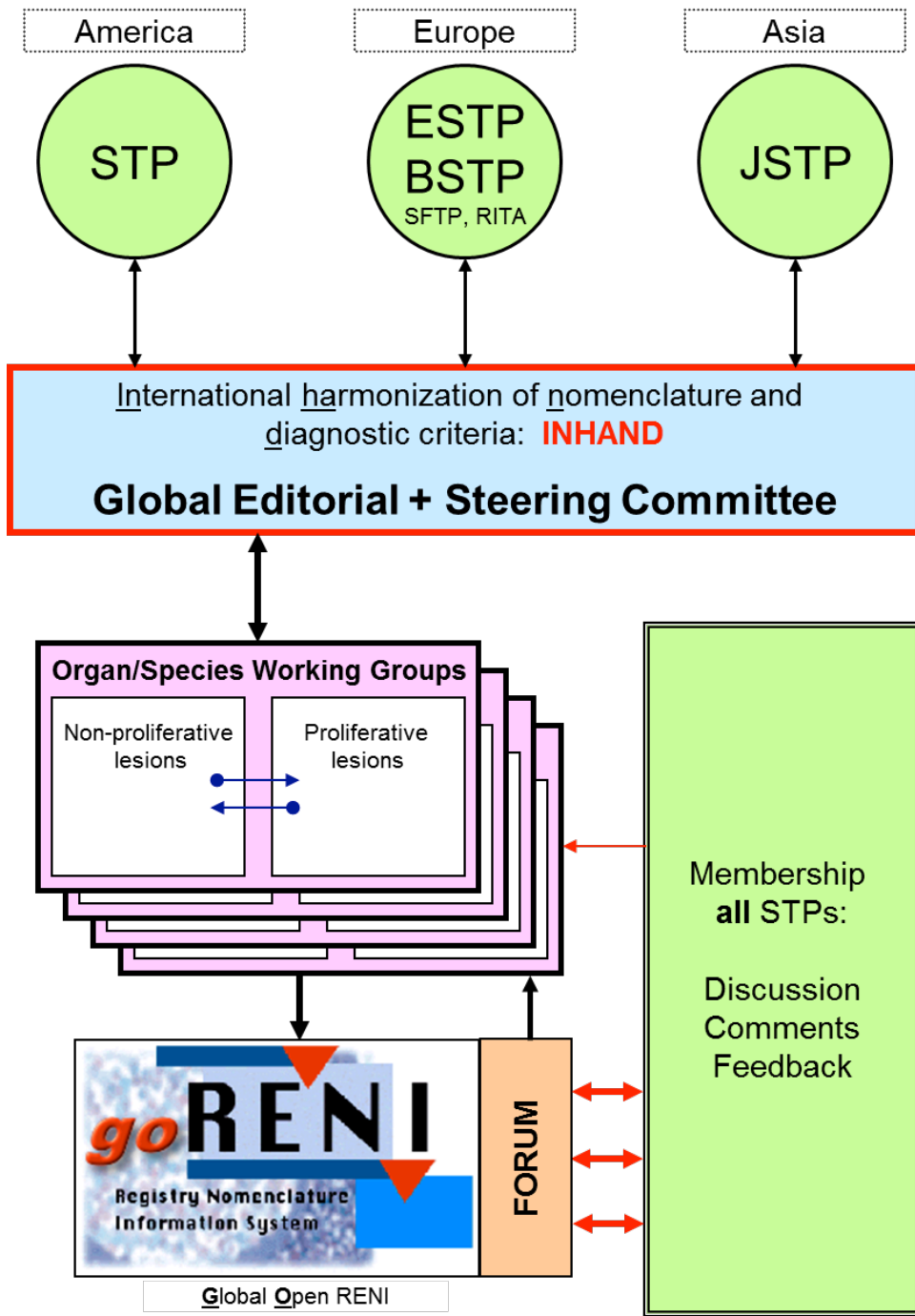
- Nominations to fill departures or vacancies on a Working Group can come from the volunteer list supplied by Society Headquarters or the from the leaders or general membership of the sponsoring societies
- Working Group Chairs submit a final list of new committee members for approval by the GESC. The GESC should select members to represent diversity of geography and sponsoring societies, while engaging appropriate subject matter expertise
- Working Group terms begin in June or at the discretion of the GESC.

GESC Reports

- The GESC submits an Annual Report to sponsoring societies by May 1 of each year
- Reports should include committee membership, a summary of committee accomplishments, issues/concerns (if any), future goals/plans, and any action items for sponsoring societies.

Budget

- Committee budget requests are due on May 1st for the following year
- Each Working Group's budget should include expenses for operations (e.g. staff administrative support, teleconferences), initiatives, and miscellaneous (e.g. breakfast or lunch at the annual meeting)
- This information is provided to the sponsoring societies to facilitate funding for INHAND activities
- If additional expenses arise that exceed the approved budget, the GESC may request additional funds with justification and may be made to one or more of the sponsoring societies.
- Budgets should project publications for the following year, but detailed costs for each publication are not required.



Organization of GESC and Working Groups