

European Society of Toxicologic Pathology e.V.

Minutes of the Annual General Assembly held on 12th September 2012, 5.30-7.30 pm
Stresa, Italy

58 members attended

- 1. Welcome and Introductory Remarks**

The meeting was opened by the Chairman, Annette Romeike. She warmly welcomed the members to the meeting and stated that the invitation had followed the rules set by the constitution and thus the assembly had a quorum.

She thanked our secretary, Francesco Marchesi, for his support and valuable organization of the Annual General Assembly.
- 2. Approval of Agenda**

The agenda was approved with an additional item about the status of the Global Nomenclature Project and Collaboration with the FDA on SEND which was presented by Susanne Rittinghausen.
- 3. Approval of Minutes from AGA Uppsala 2011**

The minutes of the last Annual General Assembly held at the 9th ESTP congress in Uppsala Sweden in 2011 had been circulated to the membership by e-mail on 21 November 2011, and were accepted by the membership as a true record.
- 4. Annual Report of the Executive Committee**

Annette Romeike presented a summary of the ESTP Executive Committee (EC) activities.

She indicated that the EC has spent a lot of effort during the past year on decisions and actions regarding the journal. A dedicated group (the Journal Task Force) led by Birgit Kittel made a clear conclusion after receiving the feedback from the membership which will be presented later on. The second main initiative was for the first time the implementation of the electronic voting for the 2012 elections of the EC members. Presentation of the process and the results will be also given during the AGA.

She informed the membership that the EC will launch a call for volunteers to support and lead new initiatives. It has been decided to expand our areas of interest beyond standard toxicology pathology. The EC believes it is important to have committees or interest groups focusing on 1 – relationship and cooperation with the clinical pathology community; 2 – the future of toxicology pathology; 3 – novel technologies as presented next year in Ghent like animal models and *in vitro* systems.

She mentioned that ESTP will bring further its strong commitment to the INHAND initiative and a new project called SEND will be presented in details by Susanne Rittinghausen.
- 5. Questions to the pre-circulated reports of the respective Committees and Councillors**

There were no questions from the membership on pre-circulated annual reports of Councillors and Committees.
- 6. Financial Report**

The financial report was presented by Matthias Rinke. He explained the details of credits and debits to the membership.

Balance on 31 December 2011: 24.223,53 € (credits August – December 2011: 7.942,33 €, debits: 24.223,53 €)

Balance on 15 August 2012: 36.108,85 € (credits January – August 2012: 36.108,85 €, debits: 22.941,50 €)

Matthias got a satisfactory income from membership fees. He has spent some effort during the last years tackling the non-paying members and now the situation is clean. The 2012 edition of the Classical Examples seminar gave us a good income. Furthermore, he informed about the financial details of past congresses: in Uppsala we had a plus of 398,70 €; the details of the congress in The Hague 2009 have still to be communicated; for the current congress in Stresa, Francesco expects to have a balanced budget. This is a very good news given the difficult situation in early July with an overall decrease of sponsors and exhibitors.

The Financial Report can be found in the list of AGA documents available in the members only area of the ESTP website.

7. 2012 Elections of the Executive Committee – Presentation of results of the electronic voting process

Annette Romeike presented the results of our first electronic voting process via the ESTP website in order to allow all ESTP members (also those unable to attend the Annual General Assembly in Stresa) to submit their vote for the elections of representatives. She thanked Wolfgang Kaufmann for having initiated this change and led the elections.

The results of the Electronic Voting process were as follows:

Position	Elected candidate
Designated chairman	Jenny McKay
Vice Chairman	Lars Mecklenburg
Secretary	Francesco Marchesi
Treasurer	Matthias Rinke
Councillor, University Professor	Wolfgang Baumgärtner
Councillor for the Younger Generation	Sibylle Gröters
Councillor for the Journal	Birgit Kittel
Councillor for IFSTP	Paul-Georg Germann
Councillor for Electronic Communication	Rupert Kellner

The detailed results of the Electronic Voting process and the composition of the ESTP Executive Committee board for the 2012-2014 term are displayed in Appendix 1.

8. Report of the Auditors (Exoneration of EC)

Unfortunately Agnes Schulte and Daniel Roth were not able to attend our meeting. But in advance, they reported that they have checked all balance sheets and confirmed the adequacy of the presentation, which is a true view of the treasury. They recommended acceptance of the accounts. The members accepted the accounts unanimously and granted exoneration of the EC.

The statement of the Auditors can be found in the list of AGA documents available in the members only area of the ESTP website.

9. **New members** Francesco Marchesi presented the list of New Members (16). They were accepted into the Society without objection.

The following colleagues have joined our society:

Name	Entry date
1. Iris Voelker	17 November 2011
2. Elena Riccardi	16 December 2011
3. Kerstin Wäse	20 January 2012
4. LuAnn McKinney	20 January 2012
5. Anna Lanzoni	20 January 2012
6. Mahesh Ganpat Brahmankar	20 January 2012
7. Daniela Pesce	20 January 2012
8. Stephanie Kristin Klein	20 January 2012
9. Aude Roulois	20 April 2012
10. Phaedra Irene Cole	20 April 2012
11. Joost Lensen	20 April 2012
12. Thierry Flandre	20 April 2012
13. Robert Johnson	4 June 2012
14. Maria Risalde	19 June 2012
15. Renata Valaskova	12 September 2012
16. Andrea Grasseti	12 September 2012

In total the ESTP comprises 298 members in September 2012. This includes few exclusions for non-payment of the fees, colleagues who resign following professional retirement. Recently the resignation of one of our members has been due to the feeling that clinical pathology was not adequately represented within the society.

10. **Election of sister societies or other bodies to be represented on the Executive Committee** The following societies have been renominated and were unanimously accepted by the membership:
- British Society of Toxicologic Pathology
 - French Society of Toxicologic Pathology
 - Dutch Society of Toxicologic Pathology
 - Hungarian Society of Toxicology
 - Italian Society of Toxicologic and Experimental Pathology
11. **Election/Ratification Representatives for Sister Societies** The following representatives were confirmed:
- Franck Chanut as representative of the British Society
 - Frieke Kuper for the Dutch Society
 - Erio Barale-Thomas as representative for the French Society
 - György Selényi for the Hungarian Society
 - Francesco Marchesi for the Italian Society
12. **Election of Auditors** Agnes Schulte and Daniel Roth volunteered to accept the nomination as Auditors again and were confirmed in their role.
13. **Membership Discussion on Important Topics** Birgit Kittel, as chair of the journal task force (which includes Annette Romeike and Paul-Georg German) reported to the membership its activities and its strategic discussion about how to continue or not with a scientific journal. During our 2011 AGA in Uppsala, a majority of our membership supported to terminate the contract with Elsevier as soon as possible. The ESTP board/journal task force was requested to explore strategic options for ESTP about association with a scientific journal or not.

On January 21, 2012, the task force sent an official request to ETP representatives in order to announce our will to terminate the contract between ESTP and ETP. Until now, despite a recommended mail to several representatives of the journal (amongst them the publisher in chief), nobody amongst the ESTP board got an official response from the editor. By chance the task force was informed about a statement that the Editorial office agreed to terminate the contract by end of the current year. An official notification is still awaited.

Birgit presented then the results of the membership questionnaire/survey on the future Journal strategy.

The membership was requested to indicate/propose journals of high value and relevance for our profession and to be potentially considered for association. 18 replies were obtained, with a total number of 51 journal nominations. Tox Path obtained 14 and was clearly above the others. The official journal of the Japanese Society of Tox Path, Journal of Toxicologic Pathology (JTP) received 5 nominations.

The Journal Task Force has considered the access of those 2 journals for the membership. The JTP is available for free online and Tox Path is provided with STP and BSTP membership. After 1 year of issue, it is available for free to everyone.

The Journal Task Force recommended to terminate the association of ESTP with a Scientific (Pathology) Journal. Of course, this recommendation was deeply discussed within the Executive Committee. It is not an easy decision and can have some consequences for our membership. However the association with a journal has limited value. The non-association might emphasize and strengthen neutrality of ESTP. Meanwhile, it is obvious that the ESTP has to maintain and expand its visibility without having a journal. For that, different actions would have to be developed and the homepage would have to be used to increase our communication. It gives us more flexibility to react quickly to emerging issues which concern our profession.

This recommendation was submitted to the vote of our membership. A total of 71 members replied. 60 answered to recommendation, 48 agreed to not further pursue journal association, 12 disagreed. Amongst those 2, 10 would favor association with Tox Path Journal. A majority of responders is already member of STP/BSTP.

Birgit Kittel confirmed our decision to no further associate ESTP with a Scientific (Pathology) Journal. The priority is now to terminate our contract with Elsevier. She thanked all her colleagues in the task force, the ESTP board, Rupert Kellner for his excellent technical assistance in organizing the vote, and she concluded by a warmly thank to Francesco as our ESTP secretary who spent a lot of effort and patience in organizing our communication.

After Birgit's presentation, the membership was given the opportunity to comment and react. Wolfgang Kaufman made the point that ESTP without a journal will have to work on its visibility. It was agreed that we are living in a changing environment and we have to be able to react quickly. Sponsoring is getting more and more difficult. Organization of the meetings is increasingly difficult, and many colleagues experience substantial constraints and shrinkage in budget for travel and meeting attendance. Those savings can be used to

implement new interest groups and take new initiatives. Our membership page has to be developed and this work was voluntarily done until now by Rupert, without any other clear support. Simultaneously it is important to maintain our visibility and actions via meetings of high quality, with good speakers, like our annual meeting, like the Classical Example in Toxicology Pathology and other scientific meetings that can be organized under the auspices of ESTP. It is urgent to terminate our contract with Elsevier. Some comments were made about the question of receiving or not the INHAND fascicles in multiple copies from Tox Path when a colleague is member of different societies (ESTP and STP or BSTP). Could we create some savings? It was concluded after a long debate that this is a heavy process for few savings, the INHAND fascicles published in Tox Path contain useful information for our daily work and it is easy to share those fascicles with younger colleagues who do not have access to them. But it was concluded that members who do not want to receive the fascicle included in their ESTP membership can easily send an e-mail to the EC, and the information will be forwarded to the editor.

14. Report of Local Organizing Committee

Francesco Marchesi offered a concise update concerning the organization of the ESTP meeting. He thanked again the valuable support of the colleagues of the Local Organizing Committee and regretted the absence of Michela Carbonatto (chair of the committee). The congress organizers, Pia Schröder and collaborators from Solution Office were also warmly acknowledged for their excellent support. He informed the audience that the congress in Stresa achieved a total of 163 registered delegates participating at the scientific sessions, plus 20 delegates registered as exhibitors, and 20 accompanying persons.

Francesco was very pleased to see some improvement in the budget status during the summer thanks to some late sponsoring, and expects to have a balanced budget.

15. Any Other Business

Susanne Rittinghausen, as ESTP Representative for Nomenclature and RITA, presented an update on the INHAND project and the new SEND initiative as collaboration with FDA.

a) The International Harmonization of Nomenclature and Diagnostic (INHAND) is a global collaboration project of STP, ESTP, BSTP and JSTP for nomenclature criteria for Lesions in Rats and Mice.

The INHAND Global Editorial Steering Committee (GESC) is chaired by Charlotte Keenan, STP. Dawn Goodman, Ron Herbert, Peter Mann and John Vahle contribute for STP. Julia Baker and Alys Bradley contribute for BSTP. Wolfgang Kaufmann, Thomas Nolte and Susanne Rittinghausen are the representative of our society (ESTP). Takanori Harada and Takuji Tanaka collaborate as JSTP contributors. The information is managed on the goRENI website by the webmaster: Rupert Kellner, Fraunhofer.

Status of INHAND manuscripts publication, listed as:
Organ System (Organ Working Group Chair).

Already published: Respiratory (Roger Renne); Liver (Bob Maronpot); Urinary (Kendall Frazier); Nervous System (Wolfgang Kaufmann).

In press: Male Reproductive (Diane Creasy); Mammary Gland,

Zymbal's Gland and Clitoral/Preputial Gland (Dan Rudmann).

Under review: Soft Tissue, Muscle and Mesothelium (Peter Greaves); Integument (Lars Mecklenburg).

In preparation: Immune (Cindy Willard-Mack); Cardiovascular (Brian Berridge); Female Reproductive (Darlene Dixon); Digestive (Thomas Nolte); Endocrine (Tom Rosol); Bone and Teeth (Joel Leininger); Special Senses (Julia Baker).

Nomenclature ready for membership review is posted on www.goreni.org. Members of each society are notified by email that the draft is posted and available for comments for a 60 day period. After the comment period is completed, the OWG consider the comments and prepare a final draft. This final draft is reviewed once more by the GESC and posted on goRENI. When an Organ System Working Group (OWG) has completed a draft of its nomenclature, the draft (with illustrations) is submitted to the GESC for initial approval and then posted on goRENI.

In addition to posting on goRENI completed nomenclature for each organ system will be/has been published in Toxicol Pathol journal.

b) in a second part Susanne Rittinghausen presented the recent collaboration with the FDA on SEND (Standard for the Exchange of Nonclinical Data).

FDA is developing a mechanism whereby Pharm Tox reviewers can electronically review, search and mine the data they receive from all non-clinical safety studies. This will be accomplished using software that will convert all electronically submitted data for a drug development program, into a standardized format, so that it can be searched within a study, across studies within a program, or across different programs. The standardized nomenclature will apply to data such as clinical signs, clinical pathology and macroscopic and microscopic anatomic pathology findings. STP is collaborating with FDA, to utilize the INHAND nomenclature as the basis for the standardized terminology.

During 2011, the INHAND Global Editorial Steering Committee (GESC) had discussions with representatives of FDA Center for Drug Evaluation and Research (CDER) and members of the Clinical Data Interchange Standards Consortium (CDISC) to examine the potential use of INHAND terminology in the software being developed for standardized nonclinical data submission to the FDA. CDISC is a global, open, non-profit, multidisciplinary organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.

In the first phase of the project (2012-2014), GESC will assist the SEND Controlled Terminology (CT) Committee in setting up appropriate categories to segment (bucket) microscopic terminology and help provide appropriate definitions for each category. GESC will map the current published terminology to the SEND codelist, i.e. map the INHAND terminology to the appropriate 'buckets' for SEND.

In a second phase, GESC will have to address the nomenclature of other species done on a species by species: dog, monkey, rabbit and minipig.

GESC will become a permanent standing committee of the various

STP's with a defined appointment and term of members. Rotation of GESC members for a 3-year period is proposed by STP. The mode for ESTP members has to be discussed.

Susanne informed the membership that we are kindly invited to participate if we are interested in joining a working group. Contact GESC members of the ESTP !

Francesco Marchesi
Secretary, ESTP

Frédéric Schorsch
Chairman, ESTP